History of Laws and Regulations Affecting the Transfer of Intellectual Property

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Introduction

The concept that *intellectual property*—the products of the mind—had a value as property arose during the framing of the U. S. Constitution. That concept grew out of extensive thought and correspondence between James Madison, the primary architect of the Constitution, and Thomas Jefferson.

Madison recognized that the nature of an individual piece of intellectual property is such that it could be useful to all people and yet could be owned by one person. That ownership, if exercised under the generic term *property* in the Fifth Amendment, could amount to indefinite monopolization of that property by the owner. On the other hand, such property, being of value to all, was susceptible of being appropriated in the public interest without just compensation to the individual who was the inventor or author. In Madison's words, "….the (creative) few will be unnecessarily sacrificed to the many."

To solve this dilemma, a compromise was struck under which intellectual property was to be owned for only a limited time during which the creator had the right to exclude others. That compromise is stated in Article I, Section 8, Clause 8, of the Constitution in the following language: "The Congress shall have Power … To promote the Progress of Science and useful arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

This constitutional provision forms the basis for the protection of intellectual property in the United States.

University technology transfer grew out of a recognition of the contribution university research had made to the technological advances during World War II and that the support of basic science by the government at universities afforded a vehicle for enhancing the economy by increasing the flow of knowledge to be used by industry.

Current university technology transfer practices evolved from a time in the 1960s when there was no uniform government patent policy and government agencies took title to all inventions made with government funds, through the persistent efforts of a few universities and far-sighted and progressive individuals in government and the Congress. This evolution passed through

- trial efforts under existing agency regulations to have title to inventions transferred to the university on a case-by-case basis;
- the negotiation and implementation of Institutional Patent Agreements with, first, the Department of Health, Education and Welfare in 1968 and, then, the National Science Foundation in 1973; to
- the passage of the Bayh-Dole Act (Public Law 96-517)[1] in 1980. The terms and provisions of the Bayh-Dole Act were, essentially, the terms and provisions of the Institutional Patent Agreements negotiated earlier.

Patents[2]

The Bayh-Dole Act and subsequent amendments provide the basis for current university technology transfer practices. The federal patent and licensing policy was shaped by four events that occurred between 1980 and 1985.

Public Law 96-517

On December 12, 1980, P.L. 96-517, the Bayh-Dole Act, was signed into law to become effective in July of 1981. This statute contains several important provisions

- for the first time, it established a uniform federal patent policy;
- universities were encouraged to collaborate with commercial concerns to promote the utilization of inventions arising from federal funding;
- it was clearly stated that universities may elect to retain title to inventions conceived or reduced to practice utilizing government funding;
- universities must file applications for patents on inventions they elect to own;

- the government retains a nonexclusive license to practice the invention throughout the world for governmental purposes;
- the government retains march-in rights;
- preference in licensing must be given to small business;
- uniform guidelines for granting licenses were provided; and
- preference for U.S. industry.

Not to be overlooked is that the Bayh-Dole Act is the first statutory authority for the U.S. government, through its agencies, to take title to and hold patents.

Office of Management and Budget Circular A-124

On February 10, 1982, the Office of Management and Budget issued policy guidance to federal agencies for implementing the Bayh-Dole Act. This guidance is known as OMB Circular A-124.[3] The government clarified the following provisions

- standard patent rights clauses for use in federal funding agreements,
- reporting requirements for universities electing title, and
- special federal rights in inventions.

Government Patent Policy

On February 18, 1983, a Presidential Memorandum on "Government Patent Policy" was issued. It mandated broad application of the new government policy.[4] Two significant aspects were

- federal agencies were directed to extend the terms and provisions of the Bayh-Dole Act to all government contractors, not only universities, nonprofit organizations, and small business; and
- the Federal Acquisition Regulations (FAR) were amended on March 30, 1984, to assure that all research and development agencies would implement the Bayh-Dole Act and the Presidential Memorandum.

Public Law 98-620

On November 8, 1984, the original Bayh-Dole Act was amended by Public Law 98-6205 to remove some of the politically motivated restrictions placed in the original act: (1) the term limitation on exclusive licenses was deleted and (2) the secretary of commerce was substituted for the comptroller general as the responsible party to determine "exceptional circumstances" when contractor rights might be overruled.

In summary, the Bayh-Dole Act and subsequent amendments created incentives for the government, universities, industry, and the small-business sector to engage in collaborative relationships involving the transfer of technology. It was not until 1987, however, that the provisions of the Bayh-Dole Act, P.L. 98-620, the OMB Circular, and the Presidential Memorandum were finalized in rulemaking, published by the Department of Commerce.[6] These rules specify the rights and obligations of all parties involved and constitute the operating manual for the modern technology transfer officer.

Stevenson-Wydler Technology Innovation Act (Public Law 96-480)

The Stevenson-Wydler Technology Innovation Act (P.L. 96-480) as amended by the Federal Technology Transfer Act of 1986 (FTTA), 15 U.S.C. 3710, authorized government-operated federal laboratories to enter into cooperative research and development agreements (CRADAs) with

- units of state or local governments;
- industrial organizations (including corporations, partnerships or limited partnerships, and industrial-development organizations);
- public and private organizations (including universities);
- nonprofit organizations;
- private individuals, including licensees of inventions owned by a federal agency; and
- other federal agencies.

FTTA was the direct progeny of the Bayh-Dole Act and much of its language is identical.

Omnibus Trade and Competitiveness Act[7]

The Omnibus Trade and Competitiveness Act, signed into law by President Ronald Reagan, August 23, 1988, plugged a leak in the protection of intellectual property that seriously undermined the value of many university patents. Some affects of this law follow.

- No longer can a company go off shore and practice a patented process, importing the resultant product into the United States without a license, without paying royalties, and without fear of patent infringement liability.
- Sections of this law strengthen the enforcement of a wide variety of intellectual property protection by making it easier for the owner to obtain exclusion orders from the United States International Trade Commission.
- Through this law, the Trade Act was given even sharper teeth to persuade "pirate countries" to enact and enforce laws for the protection of intellectual property.
- Another part of the law eases the burden that was attached to the filing of an application in a foreign country. Under the new law, the scope of a foreign-filing license permits "subsequent modifications, amendments, and supplements containing additional subject matter" to be sent to a foreign patent office without processing a special license. One cannot, however, provide such additional subject matter if it changes the nature of the invention or discloses national security information.

New Section 337 of the Tariff Act[8]

Intellectual property owners can more easily block imports that infringe patents, copyrights, registered trademarks, and mask works. New Section 337 of the Tariff Act considers the following acts to be unlawful

- the importation into or sale in the U.S. of articles that infringe U.S. patents or copyrights or that are made by a patented process;
- the importation into or sale in the U.S. of articles that infringe U.S. trademarks; and
- the importation of semiconductor chips that infringe registered mask works.

Section 301 of the Trade Act (19 U.S.C. 2411-2416)[9]

Section 301 of the Trade Act is used to exert pressure on foreign countries to respect and enforce rights in intellectual property. Evidence of international piracy of intellectual property should be provided to the U.S. trade representative. The U. S. trade representative

must identify foreign countries that deny "adequate and effective" intellectual property protection and that deny "fair and equitable" market access to persons relying on intellectual property protection. Countries that fail these criteria will be listed in the Federal Register, and the U.S. trade representative must initiate an investigation of these countries, the investigation to be completed within eighteen months. The U.S. trade representative also recommends sanctions to the president against those countries found to engage in "unjustifiable, unreasonable, or discriminatory" trade practices.

Cooperative Research and Technology Enhancement Act

The Cooperative Research and Technology Enhancement Act (CREATE) was signed into law on December 10, 2004, (P.L. 108.453). The new law amends 35 U.S.C. 103(c) so that patentability will not be precluded because of collaborative research conducted between researchers employed by different organizations. In that effect, the act overrules the decision in *Oddzon Products v. Just Toys*—a decision that held that derived prior art may serve as evidence of obviousness and hung like a sword of Damocles over collaborative-research activities. The purpose of the act is to promote collaborative research among different entities while, for prior art purposes, treating them as single entities provided a joint research agreement between the entities exists. Partnerships among academia, industry, and government are a growing phenomenon, and the CREATE Act is looked to as a means of fostering improved communication among researchers, cooperation in carrying out increasingly costly research, decreasing litigation, and improving innovation and investment in that process. The USPTO has issued special rules pertaining to the CREATE Act.

Copyright[10]

The United States Constitution gives Congress the authority to write laws governing original products of the mind.

Title 17 of the U.S. Code

In writing the copyright statutes under the authority of the Constitution, Congress limited the exclusive rights of the copyright owner. Title 17 of the U.S. Code contains fourteen separate sections limiting or defining the scope of the copyright owner's exclusive rights.

1790 to 1976

The first copyright act of the United States was enacted by the first Congress in 1790 and designated maps, charts, and books as the only creative forms of expression worthy of copyright protection. Comprehensive revisions were enacted in 1831, 1870, 1909, and 1976.

Just at the time the 1909 law was enacted, the new technologies of motion pictures and sound recording were making an appearance. These technological changes, and many others to follow, were the impetus for revision of the 1909 act. Several early attempts to revise the 1909 act failed, and it was not until the United States' participation in the development of and acceptance as a member in 1955 to the Universal Copyright Convention that the real efforts for revision began. In 1959, Arthur Fisher, commissioner of copyrights, wrote, "The past 50 years have brought about revolutionary technological changes in the reproduction, communication, and dissemination of 'writing' of an author...The emergence of new industries and new uses of copyright materials has radically altered the conditions under which copyright materials are created and used."[11] It took another twenty-one years before a new law was enacted.

Copyright Act of 1976

The Copyright Act of 1976[12] became effective on January 1, 1978, and was a major revision of the previous 1909 act. The major flaw of the 1909 act was that it did not contemplate the technological developments that had taken place; and, thus, the amendments made to the act to accommodate new technologies did not solve the inherent problems of the act. The 1976 act was written to allow for future technologies and to remove most of the dual-system protection of copyrights, which included state and federal statutes. Although Congress wanted to provide all protection through federal statutes with the passage of the 1976 act, gaps remain, and some protection can be obtained only under state statutes, e.g., works that are not fixed in a tangible, perceivable medium such as extemporaneous productions and speeches.

Other changes made by the 1976 Act were

- federal statutory protection upon fixation for both unpublished and published works eliminated the requirement of registering a work to obtain copyright protection for a

published work; a work qualifying as copyrightable subject matter is copyrighted and protected by the copyright laws once it can be read or communicated either directly or by a machine;

- failure to place an official notice of copyright on copies of a published work places the work in the public domain, and copyrights are lost; passage of the Berne Convention Implementation Act removed this notice requirement; and
- divisibility of the "bundle of rights" gives owners the right to divide and subdivide their rights and transfer them separately, rather than transferring all of the rights as an indivisible bundle.

Berne Convention Implementation Act of 1988

The Berne Convention Implementation Act (BCIA) of 1988 allowed the United States to become a member of the international Berne Union, which provides the maximum international copyright protection available. The convention provides uniform copyright protection for member countries and reduces formalities associated with establishing and asserting copyright rights. BCIA made several modifications to the Copyright Act of 1976, some of which were

- elimination of the requirement of the copyright notice upon publication of a work; in effect, this places all copyrightable subject matter under copyright protection; and
- requirement of registration of a copyright with the U.S. Copyright Office prior to litigation was eliminated for foreign works but not for U.S. works.

The Berne Convention states that an author shall have the right to claim authorship of his or her work and a right to object to distortion, mutilation, or modification of the work that would be harmful to the author's reputation. These rights are known as moral rights. In acceptance of the Berne Convention, the U.S. Copyright Act was not amended to expressly include the moral rights as stated in the Berne Convention, rather it was claimed that the amendments made by the BCIA did not "expand or reduce" moral rights.

Visual Artists Rights Act of 1990

In 1990, the first federal act for moral rights was passed. The Visual Artists Rights Act of 1990, effective June 1, 1991, created for authors of paintings, sculptures, and prints provides the lifetime right, with some exceptions, to

- receive credit as an author;
- prevent the use of the author's name on works not created by the author;
- prevent any intentional mutilation, distortion, or modification of the work, or prevent the use of the author's name on a work created by the author in the event of mutilation, distortion, or modification, when such change would harm the author's reputation (17 U.S.C. § 106A).

Trademarks

Trademark Act of February 20, 1905

This act authorized the registration of trademarks used in interstate commerce (as well as in commerce with foreign nations and with Indian tribes) and was of vital importance to American business. Under the protection of this law, industries were built up on the good will of a name.[13]

Trademark Act of July 5, 1946

A new trademark law, commonly known as the Lanham Act, was enacted. This law, which came into effect on July 5, 1947, repealed prior trademark laws and made a number of significant changes. Some of the changes were

- provisions for registering service marks and certification marks;
- incontestability of trademark registrations under certain conditions; and
- cancellation of registrations after sixth year if an affidavit of use is not filed during the six years.

Trademark Law Revision Act

The Trademark Law Revision Act, passed in 1989, updated provisions of the Lanham Act. The major change of this act, from a practitioner's point of view, provides for filing for trademark protection in anticipation of interstate commerce.

North American Free Trade Agreement as it Pertains to Trademark

The North American Free Trade Agreement (NAFTA) has taken away the possibility of naming a product with a geographic brand name that is primarily misdescriptive of the

place from which it comes (for example, naming a product *Boise Brand* Mashed Potatoes when the potatoes are not grown in Boise, Idaho, but, in fact, grown in Argentina). Prior to NAFTA, that was acceptable, as long as the institution could prove that the choice of brand was not deceptive and that, with sufficient advertising, customers would associate Boise Brand with the institution. Today, when choosing a name for a product that has a strong geographical connection, the technology manager should ensure that the product is made within that geographic location and that the manufacturer has no plans to relocate. If the institution has already used such a geographic brand name before NAFTA went into force, the brand may qualify for exemption under a grandfather clause, but one should act quickly to obtain a registration. (The General Agreement on Tariffs and Trade treaty also carries restrictions on certain kinds of geographic indicators.)[14,15]

Other Laws Affecting Intellectual Property

The Canada-United States Free Trade Agreement[16]

Canada and the United States entered into the Canada-United States Free Trade Agreement (FTA) in late 1987. FTA, which became an operative international obligation of the two countries at the start of 1988, is a bilateral extension of the General Agreement on Tariffs and Trade (GATT), which already governed the two countries' international trade relationships. Like GATT, FTA allowed Canada and the United States to continue to pursue their trade relations with other countries independently. The primary impact of FTA was in the area of tariff elimination. FTA established the first comprehensive international arrangement for trade in services between nations. The impact of FTA on intellectual property law was, in the result, minimal. Notwithstanding FTA, Canada and the United States continue to maintain their own intellectual property laws.

North American Free Trade Agreement [17]

On December 17, 1992, Canada, Mexico, and the United States signed the North American Free Trade Agreement (NAFTA). NAFTA seeks to create an expanded market for the goods and services produced in the three member countries to reduce trade distortions, eliminate barriers to trade and promote fair competition in their territories, and establish clear and mutually advantageous rules governing trade. NAFTA takes

priority over FTA, but provisions that Canada and the United States decided not to bring fully into NAFTA will remain operational between those two countries. Chapter 17 of NAFTA establishes detailed obligations on the parties in the area of intellectual property protection. In many cases, NAFTA sets certain minimum standards of protection that the countries' current legislation already provides. NAFTA has required amendments to the intellectual property laws of all countries to ensure that they accede to specified texts of international convention.

To provide adequate and effective protection and enforcement of intellectual property rights, each country must, at a minimum, give effect to the intellectual property chapter (Chapter 17) and to the substantive provisions of a number of international intellectual property conventions. These include the following.

- *The Paris Convention—International Convention for the Protection of Industrial Property (1883 as revised at Stockholm in 1967):* This is the most important general patent treaty. It was revised at Brussels in 1900, at Washington, D.C., in 1911; at The Hague, Netherlands, in 1925; at London, England, in 1934; at Lisbon, Portugal, in 1958; and at Stockholm, Sweden; in 1967—each revision superseding the former revision. An important aspect of the convention was establishing the right of priority, which permits an application filed in a country to utilize, as an effective filing date, the date of an application for the same invention less than twelve months earlier in another country. (This convention also applies to trademarks.)
- *The Berne Convention for the Protection of Literary and Artistic Works—The Berne Copyright Convention (1971):* The first multilateral copyright convention in history. It is based upon the principle of national treatment or assimilation under which a country agrees to give foreign authors the same protection it accords its own authors. It specifically prohibits a country from making protection conditional upon the fulfillment of any formal requirements such as registration or the use of a copyright notice. The United States acceded to the Berne Convention effective in 1989.
- *The UPOV Convention—International Convention for the Protection of New Varieties of Plants (1978 or 1991):* The purpose of the convention was to ensure to the breeder of a new plant variety that his or her prior authorization shall be required for: (1) the production for purposes of commercial marketing, (2) the offering for

sale, and (3) the marketing of the reproductive or vegetative propagating material of the variety. The UPOV Convention was ratified by the United States on January 22, 1999, and the act came into force on February 22, 1999. This action will afford strengthened protection for plant breeders and lessen the threat to breeders from piracy of the protected plant varieties and plagiaristic breeding activities.

- *The Geneva Convention for the Protection of Producers of Phonograms against Unauthorized Duplication of Their Phonograms (1971):* One of the most important aspects of NAFTA is that the disputed discriminatory provisions of 35 U.S.C. 104 was eliminated and that a party may prove an invention date in an interference proceeding by reference to inventive activity in any NAFTA member country.

NAFTA also established a term of a patent as twenty years from the filing date or seventeen years from the date of issue of the patent, whichever is longer.

General Agreement on Tariffs and Trade (GATT-Uruguay Round)—Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), Including Trade and Counterfeit Goods, Portion[18]

As with NAFTA, under the enabling GATT intellectual property legislation, all inventors in GATT signatory countries will be able to show early inventive activity in any GATT country in an interference proceeding (contest for priority of invention) to prove a date of invention or to prove a date of invention during prosecution of an application (131 Practice, 37 CFR 1.131).

A second significant item under the U.S. enabling legislation for TRIPs is that the patent term will be for a period of twenty years, beginning with the earliest filed application date (in cases where there are divisional or continuing applications). The enabling legislation does provide for extensions of time of the patent beyond twenty years from the initial filing date up to a maximum of five years in certain cases (interferences, appeals, secrecy orders) that prolong pendency time.

GATT-TRIPs also provides for the filing of a provisional application that could be an advantage for university-generated inventions. The provisional application does not

require the appendency of claims and can be filed for a fee of $100 (small entity). The provisional application establishes internal priority (the twenty-year-from-filing term would not begin to run from the date of filing the provisional application). The application can then be perfected by the filing of a second application within one year of the filing date of the provisional application to perfect the application. The provisional application would have to conform to the requirements of 35 U.S.C. 112 including the best-mode requirement. The second application must be for the same invention as that of the provisional application.

Under GATT-TRIPs, patent rights must include the exclusive right to offer for sale and to import patented goods—rights that did not exist under U.S. laws.

American Inventor's Protection Act of 1999

Although the American Inventor's Protection Act of 1999 (AIPA) deals primarily with changes in intellectual property patent laws and not directly with technology transfer per se, its terms and provisions impact the ongoing technology transfer efforts in universities in a forceful way. The act has been described as representing the most significant changes to the patent system since the passage of the 1952 Patents Act.

As is typical with many pieces of legislation, as well as with international conventions, various amendments are piecemeal made to correct technical defects or other errors, or to clarify, expand, or restrict the application of certain provisions depending upon later acquired experiences or intelligence. Such has been the case with many of the various acts and conventions referenced earlier. It is, however, not feasible for this history to document all such amendments and regulatory changes.

Suffice it to say that the law is a living thing and changes are inevitable. When, however, the changes are concentrated in a single organic act and can have a strong influence upon the technology transfer function, it is well to consider their evolutionary and practical effect.

Apart from the U.S. Patent and Trademark Office organizational and management changes and patent prosecution changes, the most important provisions of the AIPA that

can have a direct bearing upon the technology transfer function are patent-term adjustment, eighteen-month publication, reexamination reform, and prior-user rights.

Patent Term Adjustment[20]

This provision in the law is also referred to as the *patent term guarantee.* Under the law that took effect in 1995, the term of the patent was twenty years from the earliest filing date, with the prospect of the term being less than twenty years because of delays associated with processing the application.
AIPA provides three bases for adjustment of the term

- Patent and Trademark Office (PTO) failure to take certain actions within the specified statutory time frames;
- PTO failure to issue a patent within three years of actual filing date; and
- delays due to interference, secrecy orders, or successful appellate review.

The law provides for day-for-day adjustments for each failure or delay and guarantees a minimum patent term of seventeen years from issuance (the seventeen-year patent term that was in effect prior to the change in 1995 to twenty years from the date of first filing). Applicant has a responsibility to make reasonable effort to conclude examination with any unreasonable delays triggering an offset or reduction in the bases for the term adjustment. Applicant will, however, always receive a patent term of at least twenty years from the filing date.

Eighteen-Month Publication[21]

Traditionally pending patent applications were kept in confidence by the PTO, which is still the case except for the publication requirements under AIPA. Under AIPA, U.S. patent applications filed after November 29, 2000, may be published by the PTO eighteen months after filing.[22] Applicants may also elect to voluntarily publish applications filed before November 29, 2000. Certain applications will not, however, be published, namely:

- design applications,
- applications subject to secrecy order,
- provisional applications,
- where applicant requests not to publish provided the application is not filed in a country requiring publication, and

- the filing of a Request for Continues Examination will not result in the application being published.

Published applications are prior art and will be searchable online. A published application allows a patent owner to recover a reasonable royalty from a person who makes, uses, sells, or offers for sale a product or uses a process "as claimed in the published patent applications" for the period between the date of publication and date of issuance of the patent maturing from the application provided the person subject to the claim of royalty has had actual notice of the published application.

Reexamination[23]

Since 1981, any person could file a request for reexamination of an issued patent based on prior art that raises a substantial new question of patentability. If the PTO grants the request, another examination in ex parte form is conducted (no participation by a third party if that party had requested the reexamination).

Under AIPA, on patents issuing from applications filed on or after November 29, 1999, a third party requesting examination can participate to a limited extent in the reexamination process. The limitations are that

- the third-party requestor can file one written comment on each PTO action and applicant response,
- the third-party requestor can appeal to the Board of Appeals of the PTO but not to the federal circuit court, and
- the patent owner may appeal a final rejection of claims to the Board of Appeals of the PTO of the federal court of appeals and can seek a stay of any pending legislation involving any claim subject to inter partes reexamination.

Also significant is that a third-party requestor is estopped from later (e.g., in litigation) raising issues they "raised or could have raised" in the reexamination. In addition any requestor is estopped from later challenging "any fact" determined in the reexamination.

Prior-User Rights[24]

This section of AIPA creates a defense to patent infringement in lawsuits filed after November 29, 1999. The defense is limited to methods of doing or conducting business (e.g., financial and e-commerce patents). The infringing party must have

- practiced the method at least one year before the patentee filed its application and commercially exploited the method before the patentee filed its patent application, and
- a patent will not be considered invalid because of assertion of the prior-use defense.

Note

The forgoing list is not exhaustive in that many pieces of legislation, as well as judicial decisions, can have an impact on the university technology transfer process, particularly as they relate to changes affecting the patent laws and their administration, federal agency operations, including appropriations bills and national initiatives.

Summary

The Bayh-Dole Act, which forms the basis for modern technology transfer from universities, evolved over a period of about twenty years in an environment that slowly progressed from hostile to favorable and was the culmination of a long, slow, and tedious process. That act (and its terms and provisions as amended by P.L. 98-620) is as viable and timely today and for the future as when it was first signed into law in 1980. Its influence is strongly seen in the Federal Technology Transfer Act of 1986, and it has promoted the introduction of a great deal of intellectual-property-related legislation. The progeny and heritage of the Bayh-Dole Act as outlined has enabled the United States to enhance the competitiveness of the United States on a global basis and in a global economy. The terms and provisions of the act were derived through experience and hands-on practice and represent thoughtfully considered and reasonable protective mechanisms against abusive practices by university licensors and their licensees, as well as against arbitrary decisions by government, while also being considerate of the national interest. It has accomplished its aims beyond expectations because it has carefully balanced the interests of the parties affected by it: namely, the universities (as well as other nonprofit organizations and small business), the private sector, and the government.

The university sector has almost universally responded to the tenets of the Bayh-Dole Act. Through its activities, it has promoted a greater awareness of the university contribution to the competitiveness of the United States in a global economy and the importance of technology transfer to maintaining that competitiveness. Dissemination of the knowledge of that contribution is essential, particularly in the current climate where technological innovation has become a preferred currency in foreign affairs. The principles of Bayh-Dole must be preserved for the future well-being of the country as well as the universities. That preservation will require active efforts on its behalf; lack of institutional memory and political expediency are its enemies.

Notes

1. P.L. 96-517, Patent and Trademark Amendments Act of 1980, this law amended Title 35 U.S.C. by adding Chapter 18, Section 200-212.
2. Appreciation is extended to the Council on Governmental Relations for the material summarized in this section. This information was originally published in the brochure, *The Bayh-Dole Act, A Guide to the Law and Implementing Regulations,* produced by COGR, November 30, 1993, as a compendium piece to *University TechnologyTransfer—Questions and Answers.*
3. Office of Management and Budget Circular A-124 was subsequently codified at 37 CFR Part 401.
4. The Presidential Memorandum was incorporated into the text of Office of Management and Budget Circular A-124 on March 24, 1984.
5. P.L. 98-620 amended Chapter 18 of Title 35 U.S.C. (The Trademark Clarification Act).
6. Final rules were published on March 18, 1987, (52 FR 8552) and subsequently codified at 37 CFR Part 401.1-401.16.
7. Bremer, Howard W., et al., "Trends in Intellectual Property Law," *AUTM Journal,* Volume II, 1990, pg. 57.
8. Ibid., pg. 58.
9. Ibid., pg. 60.

10. Material contained in this section was extracted from "Copyright," by Nita Lovejoy, in the *AUTM Technology Transfer Practice Manual, Second Edition.*
11. *Annual Report of the Librarian of Congress for the Fiscal Year Ending June 30, 1959: Report to the Librarian of Congress by the Register of Copyrights.*
12. The Copyright Act of 1976 is located with amendments in Title 17 of the U.S. Code.
13. *The Story of the U.S. Patent and Trademark Office,* U.S. Department of Commerce/Patent and Trademark Office, August 1988, pg. 20.
14. Lasky, Michael, senior vice president, Merchant and Gould, Minneapolis, "Does it Really Matter if Your Picante Sauce Is Made in New York City?, *Advertising and Trademark Law.*
15. This provision, through NAFTA, has become law. The interpretation of this law, however, has not yet been tested in the courts. If an institution is considering naming a product with a geographic brand name, the technology manager may wish to consult with legal counsel for an update in this area.
16. Burshtein, Sheldon, "Impact of the North American Free Trade Agreement on Canadian Intellectual Property Rights Relating to University Technology Management," *AUTM Journal,* Volume VI, 1994.
17. Ibid.
18. Effective June 8, 1995.
19. Title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999. Section B, Pub. Law 106-113, 133 Stat. 1501 (1999).
20. 35 U.S.C. § 154(b); Adjustments due to PTO delay are available for applications filed on or after May 29, 2000. Implementing regulations at 37 C.F.R.1.702-1.703(a)-(e).
21. 35 U.S.C. § 122.
22. This harmonized U.S. practice with that in the rest of the world.
23. 37 C.F.R. 1.501, 1.510-1.570.
24. 35. U.S.C. 273

The Bayh-Dole Act

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Introduction

The passage of the Bayh-Dole Act in 1980 created a new era in the public utilization of technologies developed at research colleges and universities throughout the United States. As a result of the Bayh-Dole Act, colleges and universities conducting research using funds from the federal government could now elect to retain title to inventions arising from the use of those funds. In return, research institutions became obligated to file patent applications on those inventions and to seek their commercialization and development for the public good. This chapter briefly summarizes the benefits, obligations, and procedural steps required by the Bayh-Dole Act, as well as the potential ramifications associated with noncompliance. Also included are various examples and recommendations to consider when establishing procedures for complying with Bayh-Dole.

Historical Development

Prior to 1980 and the passage of the Bayh-Dole Act, the U.S. government had yet to adopt any uniform patent policy or statute pertaining to the ownership and disposition of inventions developed through U.S. government-sponsored contracts or from federally funded research.[1] Each government agency was, therefore, left to create its own policies with respect to the intellectual property rights in such inventions and their transfer to the private sector.[2] The ultimate result was that the university and private sector were faced with the prospect of having to deal with policies from some twenty-six different agencies.[3] One constant of these policies, however, was that title to such inventions originally vested with the U.S. government unless otherwise waived.

In the absence of any uniform policy, as well as the infrastructure and resources necessary to promote and license technologies, patented technologies held by the U.S. government very rarely made it to the commercial market. It is estimated that, by 1980, the government

had accumulated in its patent portfolio more than 30,000 patents through its various agencies.[4] Of these patents, only about 5 percent were commercially licensed, with an even smaller percentage introduced into the commercial market. In contrast, the commercialization rate of inventions to which the U.S. government elected to waive title, at least with respect to those inventions waived by NASA, was consistently in the 18 percent to 20 percent range.[5] A study conducted by the Harbridge House in 1968 on federally funded patented technologies put into use in 1957 and 1962 also suggested that contractor-held inventions were 10.7 times more likely to be commercialized for the public good than government-held inventions.[6]

By 1971, it became increasingly clearer that the U.S. government needed to establish government-wide objectives and criteria for the allocation of rights to inventions developed with federal funds.[7] Through the efforts of the Kennedy administration and, later, the Nixon administration, it was realized that the presumption of ownership of patent rights to the government was not a satisfactory basis for a government patent policy and that a more flexible, government-wide policy would best serve the public interest.[8] Accordingly, it was recognized that the more title-oriented the agencies were toward federally funded inventions, the less likely it was that the technology would be used for the public good.

After years of studies, congressional debates, and the efforts of many nonprofit organizations and small businesses, the Bayh-Dole Act was passed in 1980, creating the first uniform federal intellectual property policy. The Bayh-Dole Act has since been amended twice, in 1984[9] and 2000.[10] The first amendment, P.L. 98-620 (Nov. 8, 1984), removed certain restrictions on exclusive licensing and designated the Department of Commerce as the federal agency responsible for overseeing and monitoring compliance. The second amendment, P.L. 106-404 (Nov. 1, 2000) streamlined the process by which federal agencies commercialize inventions made by their employees. The full text of the Bayh-Dole Act, as amended, may be found at 35 U.S.C. §§ 200-212, and is set forth as Exhibit A at the end of this chapter.

Application of Federal Regulations, Guidelines, and Case Law

The Bayh-Dole Act provides the statutory framework from which today's federal intellectual property policy, as it relates to inventions developed using federal funds, has been shaped. The rules and regulations under which nonprofit organizations and small businesses must operate, however, are set forth in the federal regulations. Federal regulations are written by executive agencies and contain the specifics needed to administer the statutory laws. Regulations are often highly detailed, describing exactly how to comply with statutes, which are often vaguely worded. In the case of the Bayh-Dole Act, its implementing regulations are set forth in the *Federal Register* at 37 Code of Federal Regulations Part 401 (37 C.F.R. 401), a copy of which is included as Exhibit B at the end of this chapter.

Understanding the federal regulations may, at times, be an arduous task. Although the regulations are intended to describe exactly how to comply with the statute, they often lack clarity with respect to how such rules and obligations should be interpreted to achieve the statute's stated purpose. As a result, funding agencies often issue their own guidelines suggesting how such rules and obligations should be interpreted to achieve the policies and objectives of that funding agency. The guidelines themselves do not hold the power of the rule of law, but serve more as the guiding principles under which the funding agency will anticipate performance on the part of the recipient small business or nonprofit organization. Although guidelines are not enforceable, one should appreciate that the failure to follow a funding agency's guidelines may have an impact on future funding decisions by that agency.

The application of the Bayh-Dole Act and its rules and regulations may also be impacted by decisions made by the federal courts. The federal courts are charged with the responsibility of interpreting and enforcing the laws of the United States. Their interpretations have the force of the rule of law in those regions in which they have jurisdiction. For example, a decision issued by a federal court in one federal district will have legal precedence in that district. Likewise, a federal appellate court decision in a particular circuit will have legal precedence in that federal circuit and all federal districts therein. Both the U.S. Supreme Court and the Court of Appeals for the Federal Circuit have nationwide jurisdiction and, therefore, have binding precedence throughout the United

States. Of course, the U.S. Supreme Court has jurisdiction over all federal courts so that its decisions hold precedence to all federal courts below, including the Court of Appeals for the Federal Circuit. As a result, any decision by a federal court pertaining to the application of the Bayh-Dole Act and its rules and regulations may further define the benefits and obligations associated with inventions developed using federal funds.

The following sections summarize the benefits, obligations, and procedural steps required by the Bayh-Dole Act, as well as the potential ramifications associated with noncompliance, based on the federal regulations and recent case law, agency actions, and various agency guidelines.

General Requirements

Basic Principles

In short, the Bayh-Dole Act grants small businesses and certain nonprofit organizations the right to retain title in "subject inventions" arising from federally supported research. In return, the small business or research organization must:

- Report each disclosed invention to the funding agency within two months of written disclosure of the invention to the small business or institution.[11]
- Submit a written election to retain title prior to the earlier of two years from the date of disclosure of the subject invention to the funding agency or the occurrence of a statutory bar.[12]
- File for patent protection prior to any statutory bar.[13]
- Grant a limited license to the U.S. government.[14]
- Promote the invention's utilization, commercialization, and public availability.[15]
- Not assign the invention except to an organization which has, as one of its primary functions, the management of inventions, and with the assignee subject to the same provisions as the contractor.[16]
- Share royalty income with the inventors.[17]
- Use the remaining royalty income for research and education.[18]
- Provide a preference to small businesses.[19]
- Provide a preference to U.S. industry.[20]

The failure of the small business or nonprofit organization to meet these obligations may result in the federal agency taking title to the invention or exercising its march-in rights under 35 U.S.C. § 203. In addition or alternatively, if there is a lack of compliance, the federal agency may discontinue providing federal research funds to the organization.

Exceptions

The Bayh-Dole Act does not, however, apply in all circumstances. The funding agency may require title to subject inventions to be transferred directly to the U.S. government in the following situations:

- The small business or nonprofit organization is not located in the United States or does not have a place of business in the United States or is subject to the control of a foreign government.[21]
- The funding agency determines that an exceptional circumstance exists such that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of the Bayh-Dole Act.[22]
- A federal foreign intelligence or counterintelligence authority determines that the restriction or elimination of the right to retain title is necessary to protect the security of its activities.[23]
- The funding agreement includes the operation of a federally owned, contractor-operated facility of the Department of Energy primarily dedicated to that department's naval nuclear-propulsion or weapons-related programs.[24]
- The funding agreement is with the Tennessee Valley Authority.[25]

Conversely, in no event may the funding agency require or include any provision giving the federal agency any rights to inventions made by an awardee of federal funding under a scholarship, fellowship, training grant, or other funding agreement made by a federal agency primarily for educational purposes.[26]

The Right to Retain Title

The Bayh-Dole Act grants small businesses and nonprofit organizations the right to *retain* title in subject inventions arising from federally supported research. This presumes that the small business or nonprofit organization has either already received title

or the right to receive title to the subject invention, or at least has the ability to control the transfer of title in such inventions to the appropriate entity. In the absence of an agreement with the inventor or inventor group, transferring or requiring the transfer of title to such inventions, the small business or nonprofit organization may not have any proper title to retain.

The Patent Act provides that whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may therefore obtain a patent.[27] Such right has the attribute of personal property, and may only be transferred by way of an assignment in writing.[28] As a result, title to such patent, and the rights afforded by that patent, vests in those persons properly named as inventors until otherwise assigned to another party.

It is, therefore, imperative that the small business and nonprofit organization require, by written agreement with its employees, that they disclose promptly in writing any subject invention made under contract and the assignment of at least all inventions developed during the performance of federally funded research. In most instances, this is generally accomplished through employment agreements, research contracts, or fund-disbursement agreements. However, depending solely on such agreements may not be sufficient when it is anticipated that some research may be performed by individuals who may never encounter those agreements. For example, it is common for students at research colleges and universities to assist in the performance of research. Because such students are not employees of the institution, they are often not required to enter into an agreement requiring the assignment of their rights in any inventions developed during the course of their research. If one of those students is ultimately an inventor, or worse yet a sole inventor, to an invention made using federal funds, that institution may not have any title to retain or any rights to provide to the funding agency in accordance with Bayh-Dole. To avoid such a problem and protect the government's interests, it is wise to require any researcher performing federally funded research, whether as an employee, student, or collaborator, to execute an agreement requiring that researcher to assign to the institution any inventions developed in the course of performing research sponsored by the federal government.

Subject Inventions

The rights and obligations provided under the Bayh-Dole Act apply to those inventions that are *subject inventions* within the context of the act. The term *subject invention* means any invention of a person, small business, or nonprofit organization that is a party to a funding agreement that is conceived or first actually reduced to practice in the performance of work under that funding agreement.[29] Subject inventions need not be fully funded by the federal support or specifically within the research program's statement of work.[30] The key is that the invention must have been conceived or first reduced to practice in the performance of work under that funding agreement.

Questions often arise as to whether or not an invention is a subject invention when institutions use both government and nongovernment funding to support research in the same laboratory. The government generally does not preclude institutions from accepting supplemental research funding from nongovernment resources, but expects the obligations of Bayh-Dole to remain applicable to those inventions conceived or first actually reduced to practice in the performance of the project, regardless of whether or not separate accounting between the funds was maintained.[31]

The problem arises when a laboratory is conducting overlapping studies using federal funding in one case and nongovernment funding in the other. The Bayh-Dole regulations state that if a closely related, non-government-funded project falls outside the scope of the planned and committed activities of the federally funded project, and does not diminish or distract from the performance of such activities, inventions made in performance of the non-government-funded project shall be free from the obligations of Bayh-Dole.[32] An example of such related but separate projects would be a government-funded project that aims to expand scientific understanding in a particular field, and a closely related industry-sponsored project that aims to apply this new knowledge to develop a specific usable new technology.[33] The time relationship in conducting the two projects and the use of new fundamental knowledge from one in the performance of the other are not important determinants since most inventions rest on a knowledge base built up by numerous independent research efforts extended over many years.[34] The key is that the non-government-funded project must fall outside of the planned and committed activities of the federally funded project and must not diminish or distract from such activities.

The regulations also state that an invention that is made outside of the research activities of a federally funded project would not be viewed as a subject invention because it cannot be shown to have been "conceived or first actually reduced to practice" in the performance of the federally funded project.[35] An example of this is where an instrument purchased with government funds is later used, without interference with or cost to the federally funded project, in making an invention, the expenses of which involve only nongovernment funds.[36] In this case, the important point is that the use of the instrument must not interfere with or add any cost to the government-funded project.

Because it is very difficult to establish whether or not the non-government-funded research interfered with, diminished, distracted, or caused any costs to the government funded project, several institutions have adopted co-mingling policies. These policies generally require inventions developed in laboratories having federal funds to be deemed subject inventions unless proven otherwise. Such policies are highly effective and require the researcher to provide written evidence sufficient to establish the true independence of the non-government-sponsored research from the federal funds. In situations where federal funds are used to pay overhead expenses and salaries, this is often a large hurdle to overcome.

Invention Disclosure, Election of Title, and Filing of Patent Applications

In order to retain title to a subject invention, the small business or nonprofit organization must comply with certain due-diligence and reporting requirements. These requirements include the timely disclosure of the subject invention to the funding agency, the timely election to retain title, and the timely filing of a patent application claiming the subject invention. The failure to comply with these requirements may result in the federal agency taking title to the subject invention or exercising its march-in rights under 35 U.S.C. § 203.

Such was the case in *Campbell Plastics Engineering & Mfg. Inc. v. Brownlee,* 389 F.3d. 1243 (Fed. Cir. 2004). Campbell Plastics entered into an agreement with the Army to develop certain components of an aircrew protective mask as part of a program for small disadvantaged businesses.[37] Included in this agreement where several clauses incorporating the rights and obligations afforded under Bayh-Dole.[38] Campbell Plastics ultimately

developed a subject invention during the performance of this research, but disclosed to the Army only in periodic reports and not in the manner as required under the agreement.[39] As a result, the Army claimed that Campbell Plastics had forfeited its title to the patent that had issued claiming the subject invention.[40] The Court of Appeals for the Federal Circuit agreed, holding that the failure by Campbell Plastics to properly disclose the subject invention in the manner required under the funding agreement effectively precluded the government from safeguarding its rights to the subject invention, namely the right to pursue foreign patent protection.[41]

It is, therefore, important that the research institution or small business take special caution to ensure that it complies with the due-diligence and reporting requirements. Care should be taken to document the actions taken so as to provide comfort to potential licensees that the due-diligence requirements have been fulfilled and to provide support in the event of an audit by the funding agency or the U.S. General Accounting Office. Such audits are usually conducted at the location of the business or institution using questionnaires, personal interviews, or by reviewing the files of the appropriate office or department. Audits and reviews also usually involve a comparison of the licensing and disclosure records of the business or institution with the federal records of the funding agencies and the U.S. Patent and Trademark's office registry of issued patents. To ensure compliance with the due-diligence requirements, some small businesses and most non-profit organizations have begun using the federal government's electronic-filing system, Interagency Edison (iEdison). IEdison allows contracting organizations and federal agencies to electronically manage extramural invention portfolios in compliance with federal rules and regulations. Additional information regarding iEdison and the participating agencies may be found at http://www.iedison.gov.

The following sections summarize the significant aspects of the due-diligence and reporting requirements required under the Bayh-Dole Act and supporting regulations.

Disclosure of Subject Inventions

The small business or nonprofit organization must disclose each subject invention to the funding agency within two months after the inventor discloses it in writing to the entity's

personnel responsible for patent matters. The disclosure to the agency must be in the form of a written report and must identify the inventors and the contract under which the invention was made. The written report must be sufficiently complete in technical detail to convey a clear understanding of the invention, to the extent known at the time, as well as its nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the invention. The disclosure must also identify any publication, sale, or public use of the invention, and whether a manuscript describing the invention has been submitted and/or accepted for publication. In addition, after disclosure to the agency, the disclosing entity must promptly notify the agency of the acceptance of any manuscript describing the invention for publication or of any planned sale or public use.[42] Requests for extension of the disclosure time may be granted at the discretion of the federal funding agency.[43]

If the small business or nonprofit organization fails to properly disclose the subject invention to the funding agency within the two-month period, the funding agency may request that the title to the subject invention be conveyed to the funding agency. Such request must be in writing and be submitted within sixty days of the date the agency learns of the failure to properly disclose.[44]

Election to Retain Title

The small business or nonprofit organization must elect in writing whether or not to retain title to any subject invention by notifying the funding agency within two years of disclosure to the funding agency. However, in any case where publication, sale, or public use has initiated the one-year statutory period, the agency may shorten the period for election of title to a date that is no more than sixty days prior to the end of the statutory period. [45] Requests for an extension of time may be granted at the discretion of the federal funding agency.[46]

If the small business or nonprofit organization fails to properly elect to retain title within the two-year period, the funding agency may request that title to the subject invention be conveyed to the funding agency. Such request must be in writing and submitted no later

than sixty days of the date the agency learns of the failure to properly elect to retain title.[47] In the event that title is conveyed to the funding agency, the small business or nonprofit organization will retain a nonexclusive, royalty-free license throughout the world to that subject invention.[48] Such license extends to domestic subsidiaries and affiliates, and may be transferred only upon approval of the funding agency.

If the small business or nonprofit organization decides against retaining title to a subject invention, then the right to elect to retain title passes to the funding agency. If the funding agency decides not to elect to retain title, then the inventor may petition the funding agency to allow the inventor to retain title to the subject invention. The decision to allow an inventor the right to retain title lies solely with the funding agency, however, the funding agency must consult with the small business or nonprofit organization prior to making its determination.[49] If the inventor is granted the right to retain title, he or she will still remain obligated to those elements of Bayh-Dole that will protect the U.S. government interest in the subject invention, including requiring the inventor to file appropriate patent applications and to provide a preference to U.S. industries and small businesses.[50]

The small business and nonprofit organization should note, however, that Bayh-Dole does not provide them any accommodation if an inventor is allowed to retain title. As a result, the small business or nonprofit organization may not have a license to use the invention if the government allows the inventor to take title. The license back to the organization exists only if the government retains title. Consequently, it is important for small businesses and nonprofit organizations to consider policies requiring inventors who obtain such rights to grant at least research rights back to the organization.

Filing of Patent Applications

The small business or nonprofit organization must file its initial patent application on those subject inventions to which it elects to retain title within one year after election of title or, if earlier, prior to the end of any statutory period wherein valid patent protection can be obtained in the United States after a publication, sale, or public use.[51] The small business or nonprofit organization must file patent applications in additional countries or international patent offices within either ten months of the corresponding initial patent

application, or no longer than six months after the date the commissioner of patents and trademarks grants permission to file foreign patent applications when such filing was previously prohibited by a secrecy order.[52] The federal funding agency may grant extensions at its discretion.[53]

In addition, all patent applications and issued patents must cite at the beginning of the description that the invention was made using federal funds and that the U.S. government has certain rights in the invention.[54] An example of a typical citation is as follows: "This invention was made with government support provided under grant (contract) number X awarded by (agency name). The U.S. government has certain rights in this invention."

The requirements on due diligence do not end once the application is filed. If the small business or nonprofit organization determines not to continue the prosecution of a patent application or the payment of maintenance fees on a patent or the defense in reexamination or opposition proceeding on a patent, then written notice of such a determination must be provided to the funding agency within thirty days before the expiration of the response period required by the relevant patent office.[55] The funding agency may then take title in those countries where the small business or nonprofit organization fails to file for patent protection in a timely manner.[56] The funding agency may also take title in those countries where the small business or nonprofit organization decides not to continue prosecuting the application for, or the payment of maintenance fees on, or defending in reexamination or opposition, a patent on the subject invention.[57] In the event that title is conveyed to the funding agency, the small business and nonprofit organization will retain a nonexclusive, royalty-free license throughout the world to that subject invention.[58] Such license extends to domestic subsidiaries and affiliates and may be transferred only upon approval of the funding agency.

U.S. Government License

The Bayh-Dole Act requires the automatic granting to the U.S. government of a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on its behalf throughout the world any subject invention to which a small business or nonprofit organization has elected to retain title.[59] Such a license allows government researchers to

use the technology without having to pay a royalty and to have a contractor produce the subject invention for use by, or on behalf of, the U.S. government.[60] Third parties—contractors, grantees, and cooperative funding recipients—can use the government's licenses only when granted authority for a specific contract, grant award, or cooperative agreement that meets a federal government need.[61] The government is not entitled to automatic price discounts simply because it purchases products that incorporate inventions in which it happens to hold a license.[62] In addition, the government's rights attach only to the inventions created by the federally funded research and do not necessarily extend to later inventions based on them.[63] As a result, the government may have no rights in a next-generation invention that builds on federally funded technology if the new invention was not itself created by federally funded research.[64]

Public Availability and Commercialization Requirements

The Bayh-Dole Act obligates the nonprofit organization or small business to promote the utilization, commercialization, and public availability of those inventions in which title is retained.[65] The Bayh-Dole Act also allows the funding agency to request periodic reports, no more frequently than annually, on the utilization of subject inventions or the efforts undertaken to promote the utilization of the subject invention on the part of the small business or nonprofit organizations and their licensees.[66] Such reports must include information regarding the status of development, date of first commercial sale or use, gross royalties received, and any other data and information as the agency may reasonably specify.

To meet these obligations in a licensing setting ultimately requires the licensing entity to transfer the obligations to the licensee, while at the same time establishing a means for monitoring and ensuring that the obligations are being fulfilled by the licensee. One major concern should be that the licensed inventions will ultimately fail to make it to the commercial market, whether due to a lack of development or the intentional "shelving" of the technology by the licensee in favor of another. To avoid such events, a license agreement should include provisions that allow the license to be terminated in the event reasonable development and/or commercialization is not occurring. For example, license agreements should include a development section that requires the licensee to agree to and warrant that it actually intends to use the inventions to develop products for the commercial

market, that it will provide development reports, and that it will allow the licensor to conduct an audit to ensure that appropriate development activity is occurring. Such provisions should also be coupled with termination penalties for any failure to actively pursue the development of the inventions or to provide timely development reports or the slow introduction of the inventions to market.

Preference for United States Industry

Small businesses and nonprofit organization receiving title to subject inventions, and any assignee of such small businesses or nonprofit organization, are precluded from granting to any person or entity the exclusive right to use or sell any subject invention in the United States, unless that person or entity agrees that any products embodying the subject invention, or produced through the use of the subject invention, will be manufactured substantially in the United States.[67] However, the requirement for such an agreement may be waived in individual cases where the small business, nonprofit organization, or assignee can show the funding agency that reasonable but unsuccessful efforts were made to grant licenses on similar terms to potential licensees who could manufacture such products substantially in the United States. Alternatively, the small business, nonprofit organization, or assignee may establish that domestic manufacture is not commercially feasible under the circumstances.

Additional Requirements for Nonprofit Organizations

Prohibition on Assignment

Unlike small businesses, nonprofit organizations are precluded from assigning any rights in a subject invention without the approval of the funding agency.[68] The only exception is that the nonprofit organization may make an assignment of the subject invention to an organization that has as one of its primary functions the management of inventions.

Nonprofit organizations must use caution in drafting license agreements to ensure that such agreements do not, in effect, become assignments. Regardless of the label attached to a particular agreement, the agreement must be viewed from the standpoint of the rights afforded, as opposed to the title given to the agreement. This is important in the

context of license agreements granting exclusive rights to patents claiming inventions developed using federal funds. If a purported license grants too many rights in a technology to a licensee, the agreement may ultimately be construed to grant an assignment in violation of Bayh-Dole.

The legal definition of the term *assignment* is a "transfer or making over to another of the whole of any property, real or personal, in possession or in action, or of any estate or right therein."[69] In patent parlance, however, the term *assignment* has been given a special meaning by the U.S. Supreme Court through its decision in *Waterman v. McKenzie*. In *Waterman*, the court held:

"The patentee or his assigns may, by instrument in writing, assign, grant and convey, either, 1st, the whole patent, comprising the exclusive right to make, use, and vend the invention throughout the United States; or, 2d, an undivided part or share of that exclusive right; or, 3d, the exclusive right under the patent within and throughout a specified part of the United States. Rev. Stat. § 4898. A transfer of either of these three kinds of interests is an assignment, properly speaking, and vests in the assignee a title in so much of the patent itself, with a right to sue infringers; in the second case, jointly with the assignor; in the first and third cases, in the name of the assignee alone. Any assignment or transfer, short of one of these, is a mere license, giving the licensee no title in the patent, and no right to sue at law in his own name for infringement."[70]

In negotiating license agreements, one needs to be cognizant of the rights afforded to the licensee and its effect upon the obligations owed under the various federal laws, rules, and regulations discussed above. In the case of an exclusive license, one needs to be careful that the rights afforded to the licensee don't ultimately result in the agreement itself being construed as an assignment. In certain cases, the reservation of a single right may be enough to avoid an assignment. The Federal Circuit decisions in *Abbott Laboratories v. Diamedix Corp.* and *Vaupel Textilmaschinin KG v. Meccanica Euro Italia S.P.A.* provide the necessary analysis. In *Vaupel,* the court held:

"[T]he use of the term "exclusive license" . . . is not dispositive; what the documents in fact recite is dispositive. However, the term "assignment" has a particular meaning in patent law, implying the formal transfer of title. We conclude that the subject agreements here, although not constituting a formal assignment of the U.S. patent, were a grant of all substantial rights and . . . permitted Vaupel to sue without joining [the grantor].

A patent . . . is, in effect, a bundle of rights which may be divided and assigned, or retained in whole or part. In determining whether a grant of all substantial rights was intended, it is helpful to look at what right have been retained by the grantor, not only what was granted. The agreements show that [the grantor] retained 1) a veto right on sublicensing by Vaupel; 2) the right to obtain patents on the invention in other countries; 3) a reversionary right to the patent in the event of bankruptcy or termination of production by Vaupel; and 4) a right to receive infringement damages. . . . [N]one of these reserved rights was so substantial as to reduce the transfer to a mere license or indicate an intent not to transfer all substantial rights.

The agreements also transferred the right to sue for infringement of the . . . patent, subject only to the obligation to inform [the grantor]. This grant is particularly dispositive here."[71]

By contrast, the court in *Abbott* held that the agreement was not an assignment because Diamedix (the licensor) retained the substantial rights:

"In this case, Diamedix has retained a significantly greater interest in the patents than [the grantor] retained in *Vaupel.* Unlike in *Vaupel,* Diamedix retained a limited right to make, use, and sell products embodying the patented inventions, a right to bring suit on the patents if Abbott declined to do so, and the right to prevent Abbott from assigning its rights under the license to any party other than a successor in business."[72]

Certain provisions should be included in an agreement to avoid the agreement being construed to be an assignment. For example, one may consider adding a section reserving the right for the licensor to grant other nonprofit research institutions and governmental agencies the right to use the licensed inventions and their improvements for noncommercial

research purposes. Also consider including a termination provision allowing the agreement to be terminated if the licensee fails to commercialize the inventions by a predetermined date, or a provision precluding the licensee from assigning its rights under the license without the written consent of the licensor. Finally, one might consider maintaining the right to bring infringement actions under those patents made a subject of the license agreement.

Revenue Distribution

Nonprofit organizations are also required to share royalties with the inventors of the subject invention, including federal employee co-inventors when the funding agency deems it appropriate.[73] Bayh-Dole does not stipulate the exact amount of royalty sharing, however, most institutions outline a royalty distribution formula within their intellectual property policy. Most institutions also do not differentiate between federally funded inventions and non-federally funded inventions when determining royalty allocations.

Royalty has been broadly interpreted to include not only license fees and royalties on the sale of products, but also revenue from the sale of stock and, in limited situations, contributions made to the institution in furtherance of research. Such was the case in *Singer v. Regents of the University of California.*[74] In *Singer,* two University of California faculty inventors (Jerome Singer and Lawrence Crooks) filed suit against the University of California claiming that the university negotiated very low licensing fees with Pfizer Medical Systems in exchange for financial support to the university's research activities. The inventors claimed that they were entitled to a portion of such support in the form of a royalty allocation pursuant to the terms of their agreement with the university. A jury agreed and ultimately awarded $2.3 million in back royalties, which was later upheld on appeal. In upholding the jury verdict, the court of appeals held that the University of California breached its agreement with the inventors by renaming royalties as research funds.

Once inventor royalty shares are allocated, the balance of revenues earned with respect to a subject invention must, after payment of expenses (including payments to inventors) incidental to the administration of the subject invention, be utilized for the support of

research or education.[75] Typical expenses may include expenses associated with the filing, prosecution, and maintenance of patents claiming the subject inventions and the costs associated with securing and enforcing license agreements.

Preference for Small Business

The nonprofit organization must also make efforts that are reasonable under the circumstances to attract licensees that are small businesses and to give a preference to a small business if the organization determines that the small business has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small businesses.[76] Important in making this determination is whether or not the organization is also satisfied that the small business has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case is at the discretion of the organization.

What constitutes reasonable efforts to attract small-business licensees will vary with the circumstances and the nature, duration, and expense of efforts needed to bring the invention to the market.[77] The small-business preference is not intended, for example, to prevent nonprofit organizations from providing larger firms with a right of first refusal or other options in inventions that relate to research being supported under long-term or other arrangements with larger companies.[78] Under such circumstances, it would not be reasonable to seek and to give a preference to small-business licensees.

The assistant secretary of commerce for technology policy has the right to review the organization's licensing program and its decisions regarding small-business applicants.[79] If the secretary determines that the organization could take reasonable steps to more effectively provide a preference to small businesses, the secretary may recommend changes to the organization's licensing policies, procedures, or practices.

March-In Rights

The federal funding agency has the right to require the small business or nonprofit organization, or its assignee or exclusive licensee, to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants if the federal agency determines that:

- Necessary action has not been taken or is not expected to be taken within a reasonable time to achieve practical application[80] of the subject invention in the field of use.
- Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the small business, nonprofit organization, assignee, or their licensees.
- Such action is necessary to meet the requirements for public use specified by the federal regulations and such requirements are not reasonably satisfied by the small business, nonprofit organization, assignee or licensees.
- Such action is necessary because the obligation to provide a preference for U.S. industries has not been obtained or has been waived, or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such obligation.[81]

If the contractor, assignee, or exclusive licensee refuses such a request, the federal funding agency has the right to grant such a license itself.

Whenever a funding agency receives information that it believes might warrant the exercise of march-in rights it must, before initiating any march-in proceeding, notify the small business or nonprofit organization in writing of the information and request informal written or oral comments as well as information relevant to the matter. In the absence of any comments from the small business or nonprofit organization within thirty days, the agency may, at its discretion, proceed with the march-in procedures set forth in 37 C.F.R 401.6. If a comment is received within thirty days, or later if the agency has not initiated the relevant procedures, then the agency must, within sixty days after it receives the comment, either initiate the procedures or notify the small business or nonprofit organization, in writing, that it will not pursue march-in rights on the basis of the available information.

The march-in proceeding begins when the agency issues written notice to the small business or nonprofit organization and its assignee or exclusive licensee, if known, that the agency is considering the exercise of march-in rights. The notice must state the reasons for the proposed march-in, the facts upon which the action would be based, and must specify the field or fields of use in which the agency is considering requiring licensing. The notice must also advise the small business or nonprofit organization (assignee or exclusive licensee) of its rights.

To date, no federal agency has exercised its march-in rights. In fact, only twice has a federal agency been petitioned to do so. The first petition was filed in 1997 by CellPro Inc. The petition requested that the government exercise march-in rights with respect to certain patents held by the Johns Hopkins University and licensed first to Becton-Dickenson and then to Baxter Healthcare Corp.[82] CellPro asserted that such action was necessary to alleviate health or safety needs that had arisen due to a U.S. district court ruling that its stem-cell device infringed two of the patents in question. CellPro also asserted that John Hopkins and Baxter had failed to take reasonable steps to commercialize the technology. The Office of the Director for the National Institute of Health (NIH) denied the petition with respect to CellPro's lack of commercialization claim, indicating that Baxter and Johns Hopkins had taken effective steps to achieve practical application as demonstrated by Johns Hopkins' licensing activities; Baxter's manufacturing, practice, and operation of a device practicing the subject invention; the availability of the device for use by the public to the extent permitted at that time under then existing law; and the vigorous efforts being expended by Baxter in pursuing Food and Drug Administration approval. The NIH also denied the petition with respect to CellPro's claim based on health or safety needs, indicating that CellPro failed to establish the existence of any health or safety needs warranting the exercise of march-in rights.

More recently, the NIH considered several requests from members of Congress and the public to exercise march-in rights on patents owned by Abbott Laboratories Inc. pertaining to the HIV/AIDS drug, Norvir.[83] The primary concern expressed in these requests was that Abbott was overpricing the drug, thus, interfering with the practical application of the invention and causing the need for action to alleviate health and safety needs. The NIH disagreed, stating that Abbott had met the standard for achieving practical applica-

tion given the fact that the drug had been made widely available for use by patients with HIV/AIDS for at least eight years.[84] The NIH also stated that no evidence had been presented to suggest that the exercise of march-in rights would alleviate any health or safety needs given the fact that Norvir had been approved by the Food and Drug Administration as safe and effective and had been widely prescribed by physicians for its approved indications.[85] Finally, the NIH stated that the extraordinary remedy of march-in is not an appropriate means of controlling prices and that the issue of drug pricing is an issue appropriately left for Congress to address legislatively.[86]

Additional Information

The above information is not intended to be exhaustive with respect to the rights and obligations afforded under the Bayh-Dole Act. Application of the Bayh-Dole Act and its requirements is complex and constantly changing based on developing case law and the ever-changing guidelines issued by the many funding agencies. To assist in developing a better understanding of the requirements of the Bayh-Dole Act, one should be aware of the several resources available for receiving tutorials and updates regarding Bayh-Dole. The following are examples of such resources:

- *Journal of the Association of University Technology Managers™ and AUTM Newsletter™,* Association of University Technology Managers (http://www.autm.net)
- *A Tutorial on Technology Transfer in U.S. Colleges and Universities,* Council on Governmental Relations, September 2000 (http://www.cogr.edu)
- *University Technology Transfer Evolution and Revolution,* Howard Bremer for the 50th Anniversary of the Council on Governmental Relations (1998) (http://www.cogr.edu)
- *les Nouvelles—Journal of the Licensing Executive Society,* Licensing Executive Society (http://www.lesi.org)

Notes

1. "University Technology Transfer Evolution and Revolution," Howard W. Bremer for the 50th Anniversary of the Council on Government Relations (1998), page 17.
2. Ibid.
3. Ibid.
4. Ibid.

5. Ibid.
6. Ibid., pg. 18 (citing, "Government Patent Policy Study for the FCST Committee on Government Patent Policy," Harbridge House, Inc., (May 15, 1968), Vol. II, Parts II and III.)
7. Ibid.
8. Ibid.
9. P.L. 98-620, November 8, 1984
10. P.L. 106-104, December 2000
11. 35 U.S.C. § 202(c)(1); 47 C.F.R. 401.14(c)(1)
12. 35 U.S.C. § 202(c)(2)
13. 35 U.S.C. § 202(c)(3)
14. 35 U.S.C. § 202(c)(4)
15. 35 U.S.C. § 202(c)(5)
16. 35 U.S.C. § 202(c)(7)(A)
17. 35 U.S.C. § 202(c)(7)(B)
18. 35 U.S.C. § 202(c)(7)(C)
19. 35 U.S.C. § 202(c)(7)(D)
20. 35 U.S.C. § 204
21. 35 U.S.C. § 202(a)(i)
22. 35 U.S.C. § 202(a)(ii)
23. 35 U.S.C. § 202(a)(iii)
24. 35 U.S.C. § 202(a)(iv)
25. 35 U.S.C. § 201(b)
26. 35 U.S.C. § 212
27. 35 U.S.C. § 101
28. 35 U.S.C. § 261
29. 35 U.S.C. § 201(e)
30. 37 C.F.R. 401.1(a)
31. Ibid.
32. 37 C.F.R. 401.1(a)(1)
33. Ibid.
34. Ibid.

35. 37 C.F.R. 401.1(a)(2)
36. Ibid.
37. *Campbell Plastics Engineering & Mfg., Inc. v. Brownlee,* 389 F.3d. 1243, 1244 (Fed. Cir. 2004)
38. Id. at 1244
39. Id. at 1248-49
40. Id. at 1246
41. Id. at 1249
42. 37 C.F.R. 401.14(c)(1)
43. 37 C.F.R. 401.14(c)(4)
44. 37 C.F.R. 401.14(d)(1)
45. 37 C.F.R. 401.14(c)(2)
46. 37 C.F.R. 401.14(c)(4)
47. 37 C.F.R. 401.14(d)(1)
48. 37 C.F.R. 401.14(e)(1)
49. 35 U.S.C. 202(d)
50. 37 C.F.R. 401.9
51. 37 C.F.R. 401.14(c)(3)
52. 37 C.F.R. 401.14(c)(3)
53. 37 C.F.R. 401.14(c)(4)
54. 37 C.F.R. 401.14(f)(4)
55. 37 C.F.R. 401.14(f)(3)
56. 37 C.F.R. 401.14(d)(2)
57. 37 C.F.R. 401.14(d)(3)
58. 37 C.F.R. 401.14(e)(1)
59. 35 U.S.C. § 202(c)(4)
60. *Technology Transfer: Agencies' Rights to Federally Sponsored Biomedical Inventions,* U.S. General Accounting Office: Report to Congressional Committees, pg. 5 (July 2003)
61. Id. at pg. 6
62. Id. at pg. 7
63. Ibid.

64. Id. at pg. 8
65. 35 U.S.C. 200
66. 37 C.F.R. 401.14(h)
67. 35 U.S.C. 204
68. 35 U.S.C. §202(c)(7)(A)
69. *Black's Law Dictionary* (6th ed. 1991).
70. *Waterman v. McKenzie,* 138 U.S. 252, 255 (1891)
71. *Vaupel Textilmaschinin KG v. Meccanica Euro Italia S.P.A.,* 944 F.2d 870, 875-76 (Fed. Cir. 1991) (citations omitted).
72. *Abbott Laboratories v. Diamedix Corp.,* 47 F.3d. 1128, 1132 (Fed. Cir. 1995)
73. 35 U.S.C. 202(c)(7)(B)
74. *Singer v. Regents of the University of California,* 40 U.S.P.Q.2d 1035 (Cal. Sup. Ct., July 19, 1996), motion for JNOV granted 1996 WL684372 (Cal. Sup. Ct., September 24, 2996), JNOV reversed by Court of Appeals (1997).
75. 35 U.S.C. §202(c)(7)(C)
76. 35 U.S.C. §202(c)(7)(D)
77. 37 C.F.R. 401.7(a)
78. Ibid.
79. 37 C.F.R. 401.7(b)
80. The term *practical application* means to manufacture in the case of a composition of product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms. 37 C.F.R. 401.2(e).
81. 35 U.S.C. 203(a)
82. In re Petition of CellPro, Inc., NIH Office of the Director (August 1, 1997)
83. In the case of Norvir® Manufactured by Abbott Laboratories, Inc., NIH Office of the Director (July 29, 2004).
84. Id. at 4-5
85. Id. at 5
86. Id. at 5

Exhibit A:

Full Text of the Bayh-Dole Act (35 U.S.C. 200-212)

CHAPTER 18 — PATENT RIGHTS IN INVENTIONS MADE WITH FEDERAL ASSISTANCE

SEC.

§ 200 Policy and objective

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government

and protect the public against nonuse of unreasonable use of inventions; and to minimize the costs of administering policies in this area.

(Dec. 12, 1980, Pub.L. 96-517, §6, 94 Stat. 3019; Nov. 1, 2000, Pub. L. 106-404, §5,114 Stat. 1745)

§ 201 Definitions

As used in this chapter –

(a) The term "Federal agency" means any executive agency as defined in section 105 of title 5, and the military departments as defined by section 102 of title 5.

(b) The term "funding agreement" means any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government. Such term includes any assignment, substitution or parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under a funding agreement as herein defined.

(c) The term "contractor" means any person, small business firm, or nonprofit organization that is a party to a funding agreement.

(d) The term "invention" means any invention or discovery which is or may be patentable or otherwise protectable under this title or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

(e) The term "subject invention" means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement: *Provided,* That in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act (7 U.S.C. 2401(d)) must also occur during the period of contract performance.

(f) The term "practical application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.

(g) The term "made" when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(h) The term "small business firm" means a small business concern as defined at section 2 or Pub. L. 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration.

(i) The term "nonprofit organization" means universities and other institutions of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

(Dec. 12, 1980, Pub.L. 96-517, §6, 94 Stat. 3019; Nov. 8, 1984, Pub. L. 98-620, §501 Stat. 3365; Nov.2, 2002, Pub. L. 107-273, §13206, 116 Stat. 1904)

§ 202 Disposition of rights

(a) Each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, elect to retain title to any subject invention: *Provided, however,* That a funding agreement may provide otherwise (i) when the contractor is not located in the United States or does not have a place or business located in the United States or is subject to the control of a foreign government, (ii) in exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter, (iii) when it is determined by a Government authority which is authorized by statute or Executive order to conduct foreign intelligence or counter-intelligence activities that the restriction or elimination of the right to retain title to any subject invention is necessary to protect the security of such activities, or (iv) when the funding agreement includes the operation of a Government-owned, contractor-operated facility of the Department of Energy primarily dedicated to that Department's naval nuclear propulsion or weapons related programs and all funding agreement limitations under this subparagraph on the contractor's right to elect title to a subject invention are

limited to inventions occurring under the above two programs of the Department of Energy. The rights of the nonprofit organization or small business firm shall be subject to the provisions of paragraph (c) of this section and the other provisions of this chapter.

(b) (1) The rights of the Government under subsection (a) shall not be exercised by a Federal agency unless it first determines that at least one of the conditions identified in clauses (i) through (iv) of subsection (a) exists. Except in the case of subsection (a)(iii), the agency shall file with the Secretary of Commerce, within thirty days after the award of the applicable funding agreement, a copy of such determination. In the case of a determination under subsection (a)(ii), the statement shall include an analysis justifying the determination. In the case of determinations applicable to funding agreements with small business firms, copies shall also be sent to the Chief Counsel for Advocacy of the Small Business Administration. If the Secretary of Commerce believes that any individual determination or pattern of determinations is contrary to the policies and objectives of this chapter or otherwise not in conformance with this chapter, the Secretary shall so advise the head of the agency concerned and the Administrator of the Office of Federal Procurement Policy, and recommend corrective actions.

(2) Whenever the Administrator of the Office of Federal Procurement Policy has determined that one or more Federal agencies are utilizing the authority of clause (i) or (ii) of subsection (a) of this section in a manner that is contrary to the policies and objectives of this chapter the Administrator is authorized to issue regulations describing classes of situations in which agencies may not exercise the authorities of those clauses.

(3) At least once every five years, the Comptroller General shall transmit a report to the Committees on the Judiciary of the Senate and House of Representatives on the manner in which this chapter is being implemented by the agencies and on such other aspects of Government patent policies and practices with respect to federally funded inventions as the Comptroller General believes appropriate.

(4) If the contractor believes that a determination is contrary to the policies and objectives of this chapter or constitutes an abuse of discretion by the agency, the determination shall be subject to the section 203(b).

(c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:

(1) That the contractor disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters, and that the Federal Government may receive title to any subject invention not disclosed to it within such time.

(2) That the contractor make a written election within two years after disclosure to the Federal agency (or such additional time as may be approved by the Federal agency) whether the contractor will retain title to a subject invention: *Provided,* That in any case where publication, on sale, or public use, has initiated the one year statutory period in which valid patent protection can still be obtained in the United States, the period for election may by shortened by the Federal agency to a date that is not more than sixty days prior to the end of the statutory period: *And provided further,* That the Federal Government may receive title to any subject invention in which the contractor does not elect to retain rights or fails to elect rights within such times.

(3) That a contractor electing rights in a subject invention agrees to file a patent application prior to any statutory bar date that may occur under this title due to publication, on sale, or public use, and shall thereafter file corresponding patent applications in other countries in which it wishes to retain title within reasonable times, and that the Federal Government may receive title to any subject inventions in the United States or other countries in which the contractor has not filed patent applications on the subject invention within such times.

(4) With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: *Provided,* That the funding agreement may provide for such additional rights, including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by

the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreements relating to weapons development and production.

(5) The right of the Federal agency to require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees: *Provided,* That any such information, as well as any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under section 203 of this chapter shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5.

(6) An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.

(7) In the case of a nonprofit organization, (A) a prohibition upon the assignment of rights to a subject invention in the United States without the approval of the Federal agency, except where such assignment is made to an organization which has as one of its primary functions the management of inventions (provided that such assignee shall be subject to the same provisions as the contractor); (B) a requirement that the contractor share royalties with the inventor; (C) except with respect to a funding agreement for the operation of a Government-owned-contractor-operated facility, a requirement that the balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, be utilized for the support of scientific research or education; (D) a requirement that, except where it proves infeasible after a reasonable inquiry in the licensing of subject inventions shall be given to small business firms; and (E) with respect to a funding agreement for the operation of a Government-owned-contractor-operated facility, requirements (i) that after payment of patenting costs, licensing costs, payments

to inventors, and other expenses incidental to the administration of subject inventions, 100 percent of the balance of any royalties or income earned and retained by the contractor during any fiscal year up to and amount equal to 5 percent of the annual budget of the facility, shall be used by the contractor for scientific research, development, and education consistent with the research and development mission and objectives of the facility, including activities that increase the licensing potential of other inventions of the facility; provided that if said balance exceeds 5 percent of the annual budget of the facility, that 75 percent of such excess shall be paid to the Treasury of the United States and the remaining 25 percent shall be used for the same purposes as described above in this clause (D); and (ii) that, to the extent it provides the most effective technology transfer, the licensing of subject inventions shall be administered by contractor employees on location at the facility.

(8) The requirements of sections 203 and 204 of this chapter.

(d) If a contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder.

(e) In any case when a Federal employee is a coinventor of any invention made with a nonprofit organization, a small business firm, or a non-Federal inventor, the Federal agency employing such coinventor may, for the purpose of consolidating rights in the invention and if it finds that it would expedite the development of the invention –

(1) license or assign whatever rights it may acquire in the subject invention to the nonprofit organization, small business firm, or non-Federal inventor in accordance with the provisions of this chapter; or

(2) acquire any rights in the subject invention from the nonprofit organization, small business firm or non-federal inventor, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction and no other transaction under this chapter is conditioned on such acquisition.

(f) (1) No funding agreement with a small business firm or nonprofit organization shall contain a provision allowing a Federal agency to require the licensing to third parties of inventions owned by the contractor that are not subject

inventions unless such provision has been approved by the head of the agency and a written justification has been signed by the head of the agency. Any such provision shall clearly state whether the licensing may be required in connection with the practice of a subject invention, a specifically identified work object, or both. The head of the agency may not delegate the authority to approve provisions or sign justifications required by this paragraph.

(2) A Federal agency shall not require the licensing of third parties under any such provision unless the head of the agency determines that the use of the invention by others is necessary for the practice of a subject invention or for the use of a work object of the funding agreement and that such action is necessary to achieve the practical application of the subject invention or work object. Any such determination shall be on the record after an opportunity for an agency hearing. Any action commenced for judicial review of such determination shall be brought within sixty days after notification of such determination.

(Dec. 12, 1980, Pub.L. 96-517, §6, 94 Stat. 3020; Nov. 8, 1984, Pub. L. 98-620, §501, 98 Stat. 3364-66; Dec. 10, 1991, Pub. L. 102-204, §10,105, Stat. 1641; Nov. 29, 1999, Pub.L. 106-113, §4732, 113 Stat. 1501A-581; Nov. 1 2000, Pub.L. 106-404, §6(1), 114 Stat. 1745; Nov. 2, 2002, Pub.L. 107-273, §13206, 116 Stat 1904.)

§ 203 March-in rights

(a) With respect to any subject invention which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such –

(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) action is necessary to alleviate health or safety needs, which are not reasonably satisfied by the contractor, assignee, or their licensees;

(3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or

(4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

(b) A determination pursuant to this section or section 202(b)(4) shall not be subject to the Contract Disputes Act (41 U.S.C. §601 et seq.). An administrative appeals procedure shall be established by regulations promulgated in accordance with section 206. Additionally, any contractor, inventor, assignee, or exclusive licensee adversely affected by a determination under this section may, at any time within sixty days after the determination is issued, file a petition in the United States Claims Court, which shall have jurisdiction to determine the appeal on the record and to affirm, reverse, remand or modify as appropriate, the determination of the Federal agency. In cases described in paragraphs (1) and (3) of subsection (a), the agency's determination shall be held in abeyance pending the exhaustion of appeals or petitions filed under the preceding sentence.

(Dec. 12, 1980, Pub.L. 96-517, §6, 94 Stat. 3022; Nov. 8, 1984, Pub. L. 98-620, §501, 98 Stat. 3367; Nov.2, 2002, Pub. L. 107-273, §13206, 116 Stat. 1904.)

§204 Preference for United States industry

Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that

any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(Dec. 12, 1980, Pub. L. 96-517, §6, 94 Stat. 3023)

§205 Confidentiality

Federal agencies are authorized to withhold from disclosure to the public information disclosing any invention in which the Federal Government owns or may own a right, title, or interest (including a nonexclusive license) for a reasonable time in order for a patent application to be filed. Furthermore, Federal agencies shall not be required to release copies of any document that is part of an application for patent filed with the United States Patent and Trademark Office or with any foreign patent office.

(Dec. 12, 1980, Pub. L. 96-517, §6, 94 Stat. 3023)

§206 Uniform clauses and regulations

The Secretary of Commerce may issue regulations that may be made applicable to Federal agencies implementing the provisions of sections 202 through 204 of this chapter and shall establish standard funding agreement provisions required under this chapter. The regulations and the standard funding agreement shall be subject to public comment before their issuance.

(Dec. 12, 1980, Pub. L. 96-517, §6, 94 Stat. 3023; Nov. 8, 1984, Pub. L. 98-620, §501, 98 Stat. 3367.)

§207 Domestic and foreign protection of federally owned inventions

(a) Each Federal agency is authorized to —

(1) apply for, obtain, and maintain patents or other forms of protection in the United States and in foreign countries on inventions in which the Federal Government owns a right, title, or interest;

(2) grant nonexclusive, exclusive, or partially exclusive licenses under federally owned inventions, royalty-free or for royalties or other consideration, and on such terms and conditions, including the grant to the licensee of the right of enforcement pursuant to the provisions of chapter 29 of this title as determined appropriate in the public interest;

(3) undertake all other suitable and necessary steps to protect and administer rights to federally owned inventions on behalf of the Federal Government either directly or through contract, including acquiring rights for and administering royalties to the Federal Government in any invention, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction, to facilitate the licensing of a federally owned invention; and

(4) transfer custody and administration, in whole or in part, to another Federal agency, of the right, title, or interest in any federally owned invention.

(b) For the purpose of assuring the effective management of Government-owned inventions, the Secretary of Commerce is authorized to—

(1) assist Federal agency efforts to promote the licensing and utilization of Government-owned inventions;

(2) assist Federal agencies in seeking protection and maintaining inventions in foreign countries, including the payment of fees and costs connected therewith; and

(3) consult with and advise Federal agencies as to areas of science and technology research and development with potential for commercial utilization.

(Dec. 12, 1980, Pub.L. 96-517, §6, 94 Stat. 3023; Nov. 8, 1984, Pub. L. 98-620, §501, 98 Stat. 3367; Nov. 1, 2000, Pub. L. 106-2404 §6(2), 114, Stat. 1745.)

§208 Regulations governing Federal licensing

The Secretary of Commerce is authorized to promulgate regulations specifying the terms and conditions upon which any federally owned invention, other than inventions owned by the Tennessee Valley Authority, may be licensed on a nonexclusive, partially exclusive, or exclusive basis.

(Dec. 12, 1980, Pub.L. 96-517, §6, 94 Stat. 3024; Nov. 8, 1984, Pub. L. 98-620, §501, 98 Stat. 3367.)

§209 Licensing federally owned inventions

(a) *Authority.* — A Federal agency may grant an exclusive or partially exclusive license on a federally owned invention under section 207(a)(2) only if —

(1) granting the license is a reasonable and necessary incentive to —

(A) call forth the investment capital and expenditures needed to bring the invention to practical application; or

(B) otherwise promote the invention's utilization by the public;

(2) the Federal agency finds that the public will be served by the granting of the license, as indicated by applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public, and that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public;

(3) the applicant makes a commitment to achieve practical application of the invention within a reasonable time, which time may be extended by the agency upon the applicant's request and the applicant's demonstration that the refusal of such extension would be unreasonable;

(4) granting the license will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws; and

(5) in the case of an invention covered by a foreign patent application or patent, the interests of the Federal Government or United States industry in foreign commerce will be enhanced.

(b) *Manufacture in the United States.* — A Federal agency shall normally grant a license under section 207(a)(2) to use or sell any federally owned invention in the United States only to a licensee who agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States.

(c) *Small business.* — First preference for the granting of any exclusive or partially exclusive licenses under section 207(a)(2) shall be given to small business firms having equal or greater likelihood as other applicants to bring the invention to practical application within a reasonable time.

(d) *Terms and conditions.* — Any licenses granted under section 207(a)(2) shall contain such terms and conditions as the granting agency considers appropriate, and shall include provisions—

(1) retaining a nontransferable, irrevocable, paid-up license for any Federal agency to practice the invention or have the invention practiced throughout the world by or on behalf of the Government of the United States;

(2) requiring periodic reporting on utilization of the invention, and utilization efforts, by the licensee, but only to the extent necessary to enable the Federal agency to determine whether the terms of the license are being complied with, except that any such report shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5; and

(3) empowering the Federal agency to terminate the license in whole or in part if the agency determines that —

(A) the licensee is not executing its commitment to achieve practical application of the invention, including commitments contained in any plan submitted in support of its request for a license, and the licensee cannot otherwise demonstrate to the satisfaction of the Federal agency that it has taken, or can be expected to take within a reasonable time, effective steps to achieve practical application of the invention;

(B) the licensee is in breach of an agreement described in subsection (b);

(C) termination is necessary to meet requirements for public use specified by Federal regulations issued after the date of the license, and such requirements are not reasonably satisfied by the licensee; or

(D) the licensee has been found by a court of competent jurisdiction to have violated the Federal antitrust laws in connection with its performance under the license agreement.

(e) *Public notice.* — No exclusive or partially exclusive license may be granted under section 207(a)(2) unless public notice of the intention to grant an exclusive or partially exclusive license on a federally owned invention has been provided in an appropriate manner at least 15 days before the license is granted, and the Federal agency has considered all comments received before the end of the comment period in response to that public notice. This subsection shall not apply to the licensing of inventions made under a cooperative research and development agreement entered into under section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a).

(f) *Plan.* — No Federal agency shall grant any license under a patent or patent application on a federally owned invention unless the person requesting the license has supplied the agency with a plan for development or marketing of the invention, except that any such plan shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5.

(Dec. 12, 1980, Pub. L. 96-517, §6, 94 Stat. 3024; Nov. 1, 2000, Pub. L. 106-404, §4,114 Stat. 1743; Nov. 2, 2002, Pub. L. 107-273, § 13206, 116 Stat. 1904.)

§ 210 Precedence of chapter

(a) This chapter shall take precedence over any other Act which would require a disposition of rights in subject inventions of small business firms or nonprofit organizations contractors in a manner that is inconsistent with this chapter, including but not necessarily limited to the following:

(1) section 10(a) of the Act of June 29, 1935, as added by title I of the Act of August 14, 1946 (7 U.S.C. 427i(a); 60 Stat. 1085);

(2) section 205(a) of the Act of August 14, 1946 (7 U.S.C. 1624(a); 60 Stat. 1090);

(3) section 501(c) of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951(c); 83 Stat. 742);

(4) section 106(c) of the National Traffic and Motor Vehicle Safety Act of 1966 (15 U.S.C. 1395(c); 80 Stats. 721);
(5) section 12 of the National Science Foundation Act of 1950 (42 U.S.C. 1871(a); 82 Stat. 360);
(6) section 152 of the Atomic Energy Act of 1954 (42 U.S.C. 2182; 68 Stat. 943);
(7) section 305 of the National Aeronautics and Space Act of 1958 (42 U.S.C. 2457);
(8) section 6 of the Coal Research Development Act of 1960 (30 U.S.C. 666; 74 Stat. 337);
(9) section 4 of the Helium Act Amendments of 1960 (50 U.S.C. 167b; 74 Stat. 920);
(10) section 32 of the Arms Control and Disarmament Act of 1961 (22 U.S.C. 2572; 75 Stat. 634);
(11) section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974 (42 U.S.C. 5908; 88 stat. 1878);
(12) section 5(d) of the Consumer Product Safety Act (15 U.S.C. 2054(d); 86 Stat. 1211);
(13) section 3 of the Act of April 5, 1944 (30 U.S.C. 323; 58 Stat. 191);
(14) section 8001(c)(3) of the Solid Waste Disposal Act (42 U.S.C. 6981(c); 90 Stat. 2829);
(15) section 219 of the Foreign Assistance Act of 1961 (22 U.S.C. 2179; 83 Stat. 806);
(16) section 427(b) of the Federal Mine Health and Safety Act of 1977 (30 U.S.C. 937(b); 86 Stat. 155);
(17) section 306(d) of the Surface Mining and Reclamation Act of 1977 (30 U.S.C. 1226(d); 91 Stat. 455);
(18) section 21(d) of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2218(d); 88 Stat. 1548);
(19) section 6(b) of the Solar Photovoltaic Energy Research Development and Demonstration Act of 1978 (42 U.S.C. 5585(b); 92 Stat. 2516);
(20) section 12 of the Native Latex Commercialization and Economic Development Act of 1978 (7 U.S.C. 178j; 92 Stat. 2533); and

(21) section 408 of the Water Resources and Development Act of 1978 (42 U.S.C. 7879; 92 Stat. 1360).

The Act creating this chapter shall be construed to take precedence over any future Act unless that Act specifically cites this Act and provides that it shall take precedence over this Act.

(b) Nothing in this chapter is intended to alter the effect of the laws cited in paragraph (a) of this section or any other laws with respect to the disposition of rights in inventions made in the performance of funding agreements with persons other than nonprofit organizations or small business firms.

(c) Nothing in this chapter is intended to limit the authority of agencies to agree to the disposition of rights in inventions made in the performance of work under funding agreements with persons other than non-profit organizations or small business firms in accordance with the Statement of Government Patent Policy issued on February 18, 1983, agency regulations, or other applicable regulations or to otherwise limit the authority of agencies to allow such persons to retain ownership of inventions, except that all funding agreements, including those with other than small business firms and nonprofit organizations, shall include the requirements established in section 202(c)(4) and section 203 of this title. Any disposition of rights in inventions made in accordance with the Statement or implementing regulations, including any disposition occurring before enactment of this section are hereby authorized.

(d) Nothing in this chapter shall be construed to require the disclosure of intelligence sources or methods or to otherwise affect the authority granted to the Director of Central Intelligence by statute or Executive order for the protection of intelligence sources or methods.

(e) The provisions of the Stevenson-Wydler Technology Innovation Act of 1980 shall take precedence over the provisions of this chapter to the extent that they permit or require a disposition of rights in subject inventions that is inconsistent with this chapter.

(Dec. 12, 1980, Pub.L. 96-517, §6, 94 Stat. 3026-3027; Nov. 8, 1984, Pub. L. 98-620, §501, 98 Stat. 3367; Oct. 20, 1986, Pub. L. 99-502, §9,100, Stat. 1796; Mar. 7, 1996, Pub.L. 104-113, §7, 110 Stat. 779; Nov. 13 1998, Pub.L. 105-393, §220(c), 112 Stat. 3625; Nov. 2, 2002, Pub.L. 107-273, §13206, 116 Stat 1904.)

§ 211 Relationship to antitrust laws

Nothing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or create any defenses to actions, under any antitrust law.

(Dec. 12, 1980, Pub. L. 96-517, §6,94 Stat. 3027).

§ 212 Disposition of rights in educational awards

No scholarship, fellowship, training grant, or other funding agreement made by a Federal agency primarily to an awardee for educational purposes will contain any provision giving the Federal agency any rights to inventions made by the awardee.

(Nov. 8, 1984, Pub. L. 98-620, §501, 98 Stat. 3368).

Exhibit B:

Full Text of the Bayh-Dole Regulations (37 C.F.R. 401 et seq.)

CODE OF FEDERAL REGULATIONS
TITLE 37—PATENTS, TRADEMARKS, AND COPYRIGHTS
CHAPTER IV—ASSISTANT SECRETARY FOR TECHNOLOGY POLICY, DEPARTMENT OF COMMERCE
PART 401—RIGHTS TO INVENTIONS MADE BY NONPROFIT ORGANIZATIONS AND SMALL BUSINESS FIRMS UNDER GOVERNMENT GRANTS, CONTRACTS, AND COOPERATIVE AGREEMENTS

SEC.

§ 401.1. Scope.

(a) Traditionally there have been no conditions imposed by the government on research performers while using private facilities which would preclude them from accepting research funding from other sources to expand, to aid in completing or to conduct separate investigations closely related to research activities sponsored by the government. Notwithstanding the right of research organizations to accept supplemental funding from other sources for the purpose of expediting or more comprehensively accomplishing the research objectives of the government sponsored project, it is clear that the ownership provisions of these regulations would remain applicable in any invention "conceived or first actually reduced to practice in performance" of the project. Separate accounting for the two funds used to support the project in this case is not a determining factor.

(1) To the extent that a non-government sponsor established a project which, although closely related, falls outside the planned and committed activities of a government-funded project and does not diminish or distract from the performance of such activities, inventions made in performance of the non-government sponsored project would not be subject to the conditions of these regulations. An example of such related but separate projects would be a government-sponsored project having research objectives to expand scientific understanding in a field and a closely related industry sponsored project having as its objectives the application of such new knowledge to develop usable new technology. The time relationship in conducting the two projects and the use of new fundamental knowledge from one in the performance of the other are not important determinants since most inventions rest on a knowledge base built up by numerous independent research efforts extending over many years. Should such an invention be claimed by the performing organization to be the product of non-government sponsored research and be challenged by the sponsoring agency as being reportable to the government as a "subject invention," the challenge is appealable as described in § 401.11(d).

(2) An invention which is made outside of the research activities of a government-funded project is not viewed as a "subject invention" since it cannot be shown to have been "conceived or first actually reduced to practice" in performance

of the project. An obvious example of this is a situation where an instrument purchased with government funds is later used, without interference with or cost to the government-funded project, in making an invention all expenses of which involve only non-government funds.

(b) This part implements 35 U.S.C. 202 through 204 and is applicable to all Federal agencies. It applies to all funding agreements with small business firms and nonprofit organizations executed after the effective date of this part, except for a funding agreement made primarily for educational purposes. Certain sections also provide guidance for the administration of funding agreements that predate the effective date of this part. In accordance with 35 U.S.C. 212, no scholarship, fellowship, training grant, or other funding agreement made by a Federal agency primarily to an awardee for educational purposes will contain any provision giving the Federal agency any rights to inventions made by the awardee.

(c) The "march-in" and appeals procedures in §§ 401.6 and 401.11 shall apply to any march-in or appeal proceeding under a funding agreement subject to Chapter 18 of Title 35, U.S.C., initiated after the effective date of this part even if the funding agreement was executed prior to that date.

(d) At the request of the contractor, a funding agreement for the operation of a government-owned facility which is in effect on the effective date of this part shall be promptly amended to include the provisions required by §§ 401.3(a) unless the agency determines that one of the exceptions at 35 U.S.C. 202(a)(i) through (iv) (§ 401.3(a)(8) through (iv) of this part) is applicable and will be applied. If the exception at § 401.3(a)(iv) is determined to be applicable, the funding agreement will be promptly amended to include the provisions required by § 401.3(c).

(e) This regulation supersedes OMB Circular A-124 and shall take precedence over any regulations dealing with ownership of inventions made by small businesses and nonprofit organizations which are inconsistent with it. This regulation will be followed by all agencies pending amendment of agency regulations to conform to this part and amended Chapter 18 of Title 35. Only deviations requested by a contractor and not inconsistent with Chapter 18 of Title 35, United States Code, may be made without approval of the Secretary. Modifications or tailoring of clauses as authorized by § 401.5 or § 401.3, when alternative provisions are used under § 401.3(a)(1) through

(4), are not considered deviations requiring the Secretary's approval. Three copies of proposed and final agency regulations supplementing this part shall be submitted to the Secretary at the office set out in § 401.16 for approval for consistency with this part before they are submitted to the Office of Management and Budget (OMB) for review under Executive Order 12291 or, if no submission is required to be made to OMB, before their submission to the Federal Register for publication.

(f) In the event an agency has outstanding prime funding agreements that do not contain patent flow-down provisions consistent with this part or earlier Office of Federal Procurement Policy regulations (OMB Circular A-124 or OMB Bulletin 81-22), the agency shall take appropriate action to ensure that small business firms or nonprofit organizations that are subcontractors under any such agreements and that received their subcontracts after July 1, 1981, receive rights in their subject inventions that are consistent with Chapter 18 and this part.

(g) This part is not intended to apply to arrangements under which nonprofit organizations, small business firms, or others are allowed to use government-owned research facilities and normal technical assistance provided to users of those facilities, whether on a reimbursable or nonreimbursable basis. This part is also not intended to apply to arrangements under which sponsors reimburse the government or facility contractor for the contractor employee's time in performing work for the sponsor. Such arrangements are not considered "funding agreements" as defined at 35 U.S.C. 201(b) and § 401.2(a) of this part.

§ 401.2 Definitions.

As used in this part—

(a) The term "funding agreement" means any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal government. This term also includes any assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under a funding agreement as defined in the first sentence of this paragraph.

(b) The term "contractor" means any person, small business firm or nonprofit organization which is a party to a funding agreement.

(c) The term "invention" means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

(d) The term "subject invention" means any invention of a contractor conceived or first actually reduced to practice in the performance of work under a funding agreement; provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance.

(e) The term "practical application" means to manufacture in the case of a composition of product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms.

(f) The term "made" when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(g) The term "small business firm" means a small business concern as defined at section 2 of Pub. L. 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this part, the size standards for small business concerns involved in government procurement and subcontracting at 13 CFR 121.5 will be used.

(h) The term "nonprofit organization" means universities and other institutions of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

(i) The term "Chapter 18" means Chapter 18 of Title 35 of the United States Code.(j) The term "Secretary" means the Assistant Secretary of Commerce for Technology Policy.

(k) The term "electronically filed" means any submission of information transmitted by an electronic or optical-electronic system.

(l) The term "electronic or optical-electronic system" means a software-based system approved by the agency for the transmission of information.

(m) The term "patent application" or "application for patent" includes a provisional or non-provisional U.S. national application for patent as defined in 37 CFR 1.9 (a)(2) and (a)(3), respectively, or an application for patent in a foreign country or in an international patent office.

(n) "The term initial patent application" means a non-provisional U.S. national application for patent as defined in 37 CFR 1.9(a)(3).

[52 FR 8554, Mar. 18, 1987, as amended at 60 FR 41812, Aug. 14, 1995]

§401.3 Use of the standard clauses at §401.14

(a) Each funding agreement awarded to a small business firm or nonprofit organization (except those subject to 35 U.S.C. 212) shall contain the clause found in § 401.14(a) with such modifications and tailoring as authorized or required elsewhere in this part. However, a funding agreement may contain alternative provisions—

(1) When the contractor is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government; or

(2) In exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of Chapter 18 of Title 35 of the United States Code; or

(3) When it is determined by a government authority which is authorized by statute or executive order to conduct foreign intelligence or counterintelligence activities that the restriction or elimination of the right to retain title to any subject invention is necessary to protect the security to such activities; or

(4) When the funding agreement includes the operation of the government-owned, contractor-operated facility of the Department of Energy primarily dedicated to that Department's naval nuclear propulsion or weapons related programs and all funding agreement limitations under this subparagraph on the contractor's

right to elect title to a subject invention are limited to inventions occurring under the above two programs.

(5) If any part of the contract may require the contractor to perform work on behalf of the Government at a Government laboratory under a Cooperative Research and Development Agreement (CRADA) pursuant to the statutory authority of 15 U.S.C. 3710a, the contracting officer may include alternate paragraph (b) in the basic patent rights clause in § 401.14. Because the use of the alternate is based on a determination of exceptional circumstances under § 401.3(a)(2), the contracting officer shall ensure that the appeal procedures of § 401.4 are satisfied whenever the alternate is used.

(b) When an agency exercises the exceptions at § 401.3(a)(2) or (3), it shall use the standard clause at § 401.14(a) with only such modifications as are necessary to address the exceptional circumstances or concerns which led to the use of the exception. For example, if the justification relates to a particular field of use or market, the clause might be modified along lines similar to those described in § 401.14(b). In any event, the clause should provide the contractor with an opportunity to receive greater rights in accordance with the procedures at § 401.15. When an agency justifies and exercises the exception at § 401.3(a)(2) and uses an alternative provision in the funding agreement on the basis of national security, the provision shall provide the contractor with the right to elect ownership to any invention made under such funding agreement as provided by the Standard Patent Rights Clause found at § 401.14(a) if the invention is not classified by the agency within six months of the date it is reported to the agency, or within the same time period the Department of Energy does not, as authorized by regulation, law or Executive Order or implementing regulations thereto, prohibit unauthorized dissemination of the invention. Contracts in support of DOE's naval nuclear propulsion program are exempted from this paragraph.

(c) When the Department of Energy exercises the exception at § 401.3(a)(4), it shall use the clause prescribed at § 401.14(b) or substitute thereto with such modification and tailoring as authorized or required elsewhere in this part.

(d) When a funding agreement involves a series of separate task orders, an agency may apply the exceptions at § 401.3(a)(2) or (3) to individual task orders, and it may

structure the contract so that modified patent rights provisions will apply to the task order even though the clauses at either § 401.14(a) or (b) are applicable to the remainder of the work. Agencies are authorized to negotiate such modified provisions with respect to task orders added to a funding agreement after its initial award.

(e) Before utilizing any of the exceptions in § 401.3(a) of this section, the agency shall prepare a written determination, including a statement of facts supporting the determination, that the conditions identified in the exception exist. A separate statement of facts shall be prepared for each exceptional circumstances determination, except that in appropriate cases a single determination may apply to both a funding agreement and any subcontracts issued under it or to any funding agreement to which such an exception is applicable. In cases when § 401.3(a)(2) is used, the determination shall also include an analysis justifying the determination. This analysis should address with specificity how the alternate provisions will better achieve the objectives set forth in 35 U.S.C. 200. A copy of each determination, statement of facts, and, if applicable, analysis shall be promptly provided to the contractor or prospective contractor along with a notification to the contractor or prospective contractor of its rights to appeal the determination of the exception under 35 U.S.C. 202(b)(4) and § 401.4 of this part.

(f) Except for determinations under § 401.3(a)(3), the agency shall also provide copies of each determination, statement of fact, and analysis to the Secretary. These shall be sent within 30 days after the award of the funding agreement to which they pertain. Copies shall also be sent to the Chief Counsel for Advocacy of the Small Business Administration if the funding agreement is with a small business firm. If the Secretary of Commerce believes that any individual determination or pattern of determinations is contrary to the policies and objectives of this chapter or otherwise not in conformance with this chapter, the Secretary shall so advise the head of the agency concerned and the Administrator of the Office of Federal Procurement Policy and recommend corrective actions.

(g) To assist the Comptroller General of the United States to accomplish his or her responsibilities under 35 U.S.C. 202, each Federal agency that enters into any funding agreements with nonprofit organizations or small business firms shall accumulate and, at the request of the Comptroller General, provide the Comptroller

General or his or her duly authorized representative the total number of prime agreements entered into with small business firms or nonprofit organizations that contain the patent rights clause in this part or under OMB Circular A-124 for each fiscal year beginning with October 1, 1982.

(h) To qualify for the standard clause, a prospective contractor may be required by an agency to certify that it is either a small business firm or a nonprofit organization. If the agency has reason to question the status of the prospective contractor as a small business firm, it may file a protest in accordance with 13 CFR 121.9. If it questions nonprofit status, it may require the prospective contractor to furnish evidence to establish its status as a nonprofit organization.

[52 FR 8554, Mar. 18, 1987, as amended at 69 FR 17301, April 2, 2004]

§401.4 Contractor appeals of exceptions.

(a) In accordance with 35 U.S.C. 202(b)(4) a contractor has the right to an administrative review of a determination to use one of the exceptions at § 401.3(a)(1) through (4) if the contractor believes that a determination is either contrary to the policies and objectives of this chapter or constitutes an abuse of discretion by the agency. Paragraph (b) of this section specifies the procedures to be followed by contractors and agencies in such cases. The assertion of such a claim by the contractor shall not be used as a basis for withholding or delaying the award of a funding agreement or for suspending performance under an award. Pending final resolution of the claim the contract may be issued with the patent rights provision proposed by the agency; however, should the final decision be in favor of the contractor, the funding agreement will be amended accordingly and the amendment made retroactive to the effective date of the funding agreement.

(b) (1) A contractor may appeal a determination by providing written notice to the agency within 30 working days from the time it receives a copy of the agency's determination, or within such longer time as an agency may specify in its regulations. The contractor's notice should specifically identify the basis for the appeal.

(2) The appeal shall be decided by the head of the agency or by his/her designee who is at a level above the person who made the determination. If the notice raises a genuine dispute over the material facts, the head of the agency or the designee shall undertake, or refer the matter for, fact-finding.

(3) Fact-finding shall be conducted in accordance with procedures established by the agency. Such procedures shall be as informal as practicable and be consistent with principles of fundamental fairness. The procedures should afford the contractor the opportunity to appear with counsel, submit documentary evidence, present witnesses and confront such persons as the agency may rely upon. A transcribed record shall be made and shall be available at cost to the contractor upon request. The requirement for a transcribed record may be waived by mutual agreement of the contractor and the agency.

(4) The official conducting the fact-finding shall prepare or adopt written findings of fact and transmit them to the head of the agency or designee promptly after the conclusion of the fact-finding proceeding along with a recommended decision. A copy of the findings of fact and recommended decision shall be sent to the contractor by registered or certified mail.

(5) Fact-finding should be completed within 45 working days from the date the agency receives the contractor's written notice.

(6) When fact-finding has been conducted, the head of the agency or designee shall base his or her decision on the facts found, together with any argument submitted by the contractor, agency officials or any other information in the administrative record. In cases referred for fact-finding, the agency head or the designee may reject only those facts that have been found to be clearly erroneous, but must explicitly state the rejection and indicate the basis for the contrary finding. The agency head or the designee may hear oral arguments after fact-finding provided that the contractor or contractor's attorney or representative is present and given an opportunity to make arguments and rebuttal. The decision of the agency head or the designee shall be in writing and, if it is unfavorable to the contractor shall include an explanation of the basis of the decision. The decision of the agency or designee shall be made

within 30 working days after fact-finding or, if there was no fact-finding, within 45 working days from the date the agency received the contractor's written notice. A contractor adversely affected by a determination under this section may, at any time within sixty days after the determination is issued, file a petition in the United States Claims Court, which shall have jurisdiction to determine the appeal on the record and to affirm, reverse, remand, or modify as appropriate the determination of the Federal agency.

§401.5 Modification and tailoring of clauses.

(a) Agencies should complete the blank in paragraph (g)(2) of the clauses at § 401.14 in accordance with their own or applicable government-wide regulations such as the Federal Acquisition Regulation. In grants and cooperative agreements (and in contracts, if not inconsistent with the Federal Acquisition Regulation) agencies wishing to apply the same clause to all subcontractors as is applied to the contractor may delete paragraph (g)(2) of the clause and delete the words "to be performed by a small business firm or domestic nonprofit organization" from paragraph (g)(1). Also, if the funding agreement is a grant or cooperative agreement, paragraph (g)(3) may be deleted. When either paragraph (g)(2) or paragraphs (g)(2) and (3) are deleted, the remaining paragraph or paragraphs should be renumbered appropriately.

(b) Agencies should complete paragraph (l), "Communications", at the end of the clauses at § 401.14 by designating a central point of contact for communications on matters relating to the clause. Additional instructions on communications may also be included in paragraph (l).

(c) Agencies may replace the italicized words and phrases in the clauses at § 401.14 with those appropriate to the particular funding agreement. For example, "contracts" could be replaced by "grant," "contractor" by "grantee," and "contracting officer" by "grants officer." Depending on its use, "Federal agency" can be replaced either by the identification of the agency or by the specification of the particular office or official within the agency.

(d) When the agency head or duly authorized designee determines at the time of contracting with a small business firm or nonprofit organization that it would be in the national interest to acquire the right to sublicense foreign governments or international organizations pursuant to any existing treaty or international agreement, a

sentence may be added at the end of paragraph (b) of the clause at § 401.14 as follows: *This license will include the right of the government to sublicense foreign governments, their nationals and international organizations, pursuant to the following treaties or international agreements: _____.*

The blank above should be completed with the names of applicable existing treaties or international agreements, agreements of cooperation, memoranda of understanding, or similar arrangements, including military agreements relating to weapons development and production. The above language is not intended to apply to treaties or other agreements that are in effect on the date of the award but which are not listed. Alternatively, agencies may use substantially similar language relating the government's rights to specific treaties or other agreements identified elsewhere in the funding agreement. The language may also be modified to make clear that the rights granted to the foreign government, and its nationals or an international organization may be for additional rights beyond a license or sublicense if so required by the applicable treaty or international agreement. For example, in some exclusive licenses or even the assignment of title in the foreign country involved might be required. Agencies may also modify the language above to provide for the direct licensing by the contractor of the foreign government or international organization.

(e) If the funding agreement involves performance over an extended period of time, such as the typical funding agreement for the operation of a government-owned facility, the following language may also be added:

The agency reserves the right to unilaterally amend this funding agreement to identify specific treaties or international agreements entered into or to be entered into by the government after the effective date of this funding agreement and effectuate those license or other rights which are necessary for the government to meet its obligations to foreign governments, their nationals and international organizations under such treaties or international agreements with respect to subject inventions made after the date of the amendment.

(f) Agencies may add additional subparagraphs to paragraph (f) of the clauses at § 401.14 to require the contractor to do one or more of the following:

(1) Provide a report prior to the close-out of a funding agreement listing all subject inventions or stating that there were none.

(2) Provide, upon request, the filing date, patent application number and title; a copy of the patent application; and patent number and issue date for any subject invention in any country in which the contractor has applied for a patent.

(3) Provide periodic (but no more frequently than annual) listings of all subject inventions which were disclosed to the agency during the period covered by the report.

(g) If the contract is with a nonprofit organization and is for the operation of a government-owned, contractor-operated facility, the following will be substituted for paragraph (k)(3) of the clause at § 401.14(a):

(3) *After payment of patenting costs, licensing costs, payments to inventors, and other expenses incidental to the administration of subject inventions, the balance of any royalties or income earned and retained by the contractor during any fiscal year on subject inventions under this or any successor contract containing the same requirement, up to any amount equal to five percent of the budget of the facility for that fiscal year, shall be used by the contractor for scientific research, development, and education consistent with the research and development mission and objectives of the facility, including activities that increase the licensing potential of other inventions of the facility. If the balance exceeds five percent, 75 percent of the excess above five percent shall be paid by the contractor to the Treasury of the United States and the remaining 25 percent shall be used by the contractor only for the same purposes as described above. To the extent it provides the most effective technology transfer, the licensing of subject inventions shall be administered by contractor employees on location at the facility.*

(h) If the contract is for the operation of a government-owned facility, agencies may add the following at the end of paragraph (f) of the clause at § 401.14(a):

(5) *The contractor shall establish and maintain active and effective procedures to ensure that subject inventions are promptly identified and timely disclosed and shall submit a description of the procedures to the contracting*

officer so that the contracting officer may evaluate and determine their effectiveness.

[52 FR 8554, Mar. 19, 1987, as amended at 60 FR 41812,Aug.14,1995]

§ 401.6 Exercise of march-in rights.

(a) The following procedures shall govern the exercise of the march-in rights of the agencies set forth in 35 U.S.C. 203 and paragraph (j) of the clause at § 401.14.

(b) Whenever an agency receives information that it believes might warrant the exercise of march-in rights, before initiating any march-in proceeding, it shall notify the contractor in writing of the information and request informal written or oral comments from the contractor as well as information relevant to the matter. In the absence of any comments from the contractor within 30 days, the agency may, at its discretion, proceed with the procedures below. If a comment is received within 30 days, or later if the agency has not initiated the procedures below, then the agency shall, within 60 days after it receives the comment, either initiate the procedures below or notify the contractor, in writing, that it will not pursue march-in rights on the basis of the available information.

(c) A march-in proceeding shall be initiated by the issuance of a written notice by the agency to the contractor and its assignee or exclusive licensee, as applicable and if known to the agency, stating that the agency is considering the exercise of march-in rights. The notice shall state the reasons for the proposed march-in in terms sufficient to put the contractor on notice of the facts upon which the action would be based and shall specify the field or fields of use in which the agency is considering requiring licensing. The notice shall advise the contractor (assignee or exclusive licensee) of its rights, as set forth in this section and in any supplemental agency regulations. The determination to exercise march-in rights shall be made by the head of the agency or his or her designee.

(d) Within 30 days after the receipt of the written notice of march-in, the contractor (assignee or exclusive licensee) may submit in person, in writing, or through a representative, information or argument in opposition to the proposed march-in, including any additional specific information which raises a genuine dispute over the material facts upon which the march-in is based. If the information presented raises a

genuine dispute over the material facts, the head of the agency or designee shall undertake or refer the matter to another official for fact-finding.

(e) Fact-finding shall be conducted in accordance with the procedures established by the agency. Such procedures shall be as informal as practicable and be consistent with principles of fundamental fairness. The procedures should afford the contractor the opportunity to appear with counsel, submit documentary evidence, present witnesses and confront such persons as the agency may present. A transcribed record shall be made and shall be available at cost to the contractor upon request. The requirement for a transcribed record may be waived by mutual agreement of the contractor and the agency. Any portion of the march-in proceeding, including a fact-finding hearing that involves testimony or evidence relating to the utilization or efforts at obtaining utilization that are being made by the contractor, its assignee, or licensees shall be closed to the public, including potential licensees. In accordance with 35 U.S.C. 202(c)(5), agencies shall not disclose any such information obtained during a march-in proceeding to persons outside the government except when such release is authorized by the contractor (assignee or licensee).

(f) The official conducting the fact-finding shall prepare or adopt written findings of fact and transmit them to the head of the agency or designee promptly after the conclusion of the fact-finding proceeding along with a recommended determination. A copy of the findings of fact shall be sent to the contractor (assignee or exclusive licensee) by registered or certified mail. The contractor (assignee or exclusive licensee) and agency representatives will be given 30 days to submit written arguments to the head of the agency or designee; and, upon request by the contractor oral arguments will be held before the agency head or designee that will make the final determination.

(g) In cases in which fact-finding has been conducted, the head of the agency or designee shall base his or her determination on the facts found, together with any other information and written or oral arguments submitted by the contractor (assignee or exclusive licensee) and agency representatives, and any other information in the administrative record. The consistency of the exercise of march-in rights with the policy and objectives of 35 U.S.C. 200 shall also be considered. In cases referred for fact-finding, the head of the agency or designee may reject only those facts that have been found to be clearly erroneous, but must explicitly state the

rejection and indicate the basis for the contrary finding. Written notice of the determination whether march-in rights will be exercised shall be made by the head of the agency or designee and sent to the contractor (assignee of exclusive licensee) by certified or registered mail within 90 days after the completion of fact-finding or 90 days after oral arguments, whichever is later, or the proceedings will be deemed to have been terminated and thereafter no march-in based on the facts and reasons upon which the proceeding was initiated may be exercised.

(h) An agency may, at any time, terminate a march-in proceeding if it is satisfied that it does not wish to exercise march-in rights.

(i) The procedures of this Part shall also apply to the exercise of march-in rights against inventors receiving title to subject inventions under 35 U.S.C. 202(d) and, for that purpose, the term "contractor" as used in this section shall be deemed to include the inventor.

(j) An agency determination unfavorable to the contractor (assignee or exclusive licensee) shall be held in abeyance pending the exhaustion of appeals or petitions filed under 35 U.S.C. 203(2).

(k) For purposes of this section the term "exclusive licensee" includes a partially exclusive licensee.

(l) Agencies are authorized to issue supplemental procedures not inconsistent with this part for the conduct of march-in proceedings.

§401.7 Small business preference

(a) Paragraph (k)(4) of the clauses at § 401.14 Implements the small business preference requirement of 35 U.S.C. 202(c)(7)(D). Contractors are expected to use efforts that are reasonable under the circumstances to attract small business licensees. They are also expected to give small business firms that meet the standard outlined in the clause a preference over other applicants for licenses. What constitutes reasonable efforts to attract small business licensees will vary with the circumstances and the nature, duration, and expense of efforts needed to bring the invention to the market. Paragraph (k)(4) is not intended, for example, to prevent nonprofit organizations from providing larger firms with a right of first refusal or other options in inventions that relate to research being supported under long-term or other arrange-

ments with larger companies. Under such circumstances it would not be reasonable to seek and to give a preference to small business licensees.

(b) Small business firms that believe a nonprofit organization is not meeting its obligations under the clause may report their concerns to the Secretary. To the extent deemed appropriate, the Secretary will undertake informal investigation of the concern, and, if appropriate, enter into discussions or negotiations with the nonprofit organization to the end of improving its efforts in meeting its obligations under the clause. However, in no event will the Secretary intervene in ongoing negotiations or contractor decisions concerning the licensing of a specific subject invention. All the above investigations, discussions, and negotiations of the Secretary will be in coordination with other interested agencies, including the Small Business Administration; and in the case of a contract for the operation of a government-owned, contractor operated research or production facility, the Secretary will coordinate with the agency responsible for the facility prior to any discussions or negotiations with the contractor.

§401.8 Reporting on utilization of subject inventions.

(a) Paragraph (h) of the clauses at § 401.14 and its counterpart in the clause at Attachment A to OMB Circular A-124 provides that agencies have the right to receive periodic reports from the contractor on utilization of inventions. Agencies exercising this right should accept such information, to the extent feasible, in the format that the contractor normally prepares it for its own internal purposes. The prescription of forms should be avoided. However, any forms or standard questionnaires that are adopted by an agency for this purpose must comply with the requirements of the Paperwork Reduction Act. Copies shall be sent to the Secretary.

(b) In accordance with 35 U.S.C. 202(c) (5) and the terms of the clauses at § 401.14, agencies shall not disclose such information to persons outside the government. Contractors will continue to provide confidential markings to help prevent inadvertent release outside the agency.

§401.9 Retention of rights by contractor employee inventor

Agencies which allow an employee/inventor of the contractor to retain rights to a subject invention made under a funding agreement with a small business firm or nonprofit

organization contractor, as authorized by 35 U.S.C. 202(d), will impose upon the inventor at least those conditions that would apply to a small business firm contractor under paragraphs (d)(1) and (3); (f)(4); (h); (i); and (j) of the clause at § 401.14(a).

§401.10 Government assignment to contractor of rights in invention of government employee.

In any case when a Federal employee is a co-inventor of any invention made under a funding agreement with a small business firm or nonprofit organization and the Federal agency employing such co-inventor transfers or reassigns the right it has acquired in the subject invention from its employee to the contractor as authorized by 35 U.S.C. 202(e), the assignment will be made subject to the same conditions as apply to the contractor under the patent rights clause of its funding agreement. Agencies may add additional conditions as long as they are consistent with 35 U.S.C. 201-206.

§ 401.11 Appeals.

(a) As used in this section, the term "standard clause" means the clause at § 401.14 of this part and the clauses previously prescribed by either OMB Circular A-124 or OMB Bulletin 81-22.

(b) The agency official initially authorized to take any of the following actions shall provide the contractor with a written statement of the basis for his or her action at the time the action is taken, including any relevant facts that were relied upon in taking the action.

(1) A refusal to grant an extension under paragraph (c)(4) of the standard clauses.

(2) A request for a conveyance of title under paragraph (d) of the standard clauses.

(3) A refusal to grant a waiver under paragraph (i) of the standard clauses.

(4) A refusal to approve an assignment under paragraph (k)(1) of the standard clauses.

(5) A refusal to grant an extension of the exclusive license period under paragraph (k)(2) of the clauses prescribed by either OMB Circular A-124 or OMB Bulletin 81-22.

(c) Each agency shall establish and publish procedures under which any of the agency actions listed in paragraph (b) of this section may be appealed to the head of the agency or designee. Review at this level shall consider both the factual and legal

basis for the actions and its consistency with the policy and objectives of 35 U.S.C. 200-206.

(d) Appeals procedures established under paragraph (c) of this section shall include administrative due process procedures and standards for fact-finding at least comparable to those set forth in § 401.6 (e) through (g) whenever there is a dispute as to the factual basis for an agency request for a conveyance of title under paragraph (d) of the standard clause, including any dispute as to whether or not an invention is a subject invention.

(e) To the extent that any of the actions described in paragraph (b) of this section are subject to appeal under the Contract Dispute Act, the procedures under the Act will satisfy the requirements of paragraphs (c) and (d) of this section.

§401.12 Licensing of background patent rights to third parties.

(a) A funding agreement with a small business firm or a domestic nonprofit organization will not contain a provision allowing a Federal agency to require the licensing to third parties of inventions owned by the contractor that are not subject inventions unless such provision has been approved by the agency head and a written justification has been signed by the agency head. Any such provision will clearly state whether the licensing may be required in connection with the practice of a subject invention, a specifically identified work object, or both. The agency head may not delegate the authority to approve such provisions or to sign the justification required for such provisions.

(b) A Federal agency will not require the licensing of third parties under any such provision unless the agency head determines that the use of the invention by others is necessary for the practice of a subject invention or for the use of a work object of the funding agreement and that such action is necessary to achieve practical application of the subject invention or work object. Any such determination will be on the record after an opportunity for an agency hearing. The contractor shall be given prompt notification of the determination by certified or registered mail. Any action commenced for judicial review of such determination shall be brought within sixty days after notification of such determination.

§401.13 Administration of patent rights clauses.

(a) In the event a subject invention is made under funding agreements of more than one agency, at the request of the contractor or on their own initiative the agencies shall designate one agency as responsible for administration of the rights of the government in the invention.

(b) Agencies shall promptly grant, unless there is a significant reason not to, a request by a nonprofit organization under paragraph (k)(2) of the clauses prescribed by either OMB Circular A-124 or OMB Bulletin 81-22 inasmuch as 35 U.S.C. 202(c)(7) has since been amended to eliminate the limitation on the duration of exclusive licenses. Similarly, unless there is a significant reason not to, agencies shall promptly approve an assignment by a nonprofit organization to an organization which has as one of its primary functions the management of inventions when a request for approval has been necessitated under paragraph (k)(1) of the clauses prescribed by either OMB Circular A-124 or OMB Bulletin 81-22 because the patent management organization is engaged in or holds a substantial interest in other organizations engaged in the manufacture or sale of products or the use of processes that might utilize the invention or be in competition with embodiments of the invention. As amended, 35 U.S.C. 202(c)(7) no longer contains this limitation. The policy of this subsection should also be followed in connection with similar approvals that may be required under Institutional Patent Agreements, other patent rights clauses, or waivers that predate Chapter 18 of Title 35, United States Code.

(c) The President's Patent Policy Memorandum of February 18, 1983, states that agencies should protect the confidentiality of invention disclosure, patent applications, and utilization reports required in performance or in consequence of awards to the extent permitted by 35 U.S.C. 205 or other applicable laws. The following requirements should be followed for funding agreements covered by and predating this Part 401.

(1) To the extent authorized by 35 U.S.C. 205, agencies shall not disclose to third parties pursuant to requests under the Freedom of Information Act (FOIA) any information disclosing a subject invention for a reasonable time in order for a patent application to be filed. With respect to subject inventions of contractors that are small business firms or nonprofit organizations, a reasonable time shall be the time during which an initial patent application may be filed

under paragraph (c) of the standard clause found at § 401.14(a) or such other clause may be used in the funding agreement. However, an agency may disclose such subject inventions under the FOIA, at its discretion, after a contractor has elected not to retain title or after the time in which the contractor is required to make an election if the contractor has not made an election within that time. Similarly, an agency may honor a FOIA request at its discretion if it finds that the same information has previously been published by the inventor, contractor, or otherwise. If the agency plans to file itself when the contractor has not elected title, it may, of course, continue to avail itself of the authority of 35 U.S.C. 205.

(2) In accordance with 35 U.S.C. 205, agencies shall not disclose or release for a period of 18 months from the filing date of the patent application to third parties pursuant to requests under the Freedom of Information Act, or otherwise, copies of any document which the agency obtained under this clause which is part of an application for patent with the U.S. Patent and Trademark Office or any foreign patent office filed by the contractor (or its assignees, licensees, or employees) on a subject invention to which the contractor has elected to retain title. This prohibition does not extend to disclosure to other government agencies or contractors of government agencies under an obligation to maintain such information in confidence.

(3) A number of agencies have policies to encourage public dissemination of the results of work supported by the agency through publication in government or other publications of technical reports of contractors or others. In recognition of the fact that such publication, if it included descriptions of a subject invention could create bars to obtaining patent protection, it is the policy of the executive branch that agencies will not include in such publication programs copies of disclosures of inventions submitted by small business firms or nonprofit organizations, pursuant to paragraph (c) of the standard clause found at § 401.14(a), except that under the same circumstances under which agencies are authorized to release such information pursuant to FOIA requests under paragraph (c)(1) of this section, agencies may publish such disclosures.

(4) Nothing in this paragraph is intended to preclude agencies from including in the publication activities described in the first sentence of paragraph (c)(3), the publication of materials describing a subject invention to the extent such materials were provided as part of a technical report or other submission of the contractor which were submitted independently of the requirements of the patent rights provisions of the contract. However, if a small business firm or nonprofit organization notifies the agency that a particular report or other submission contains a disclosure of a subject invention to which it has elected title or may elect title, the agency shall use reasonable efforts to restrict its publication of the material for six months from date of its receipt of the report or submission or, if earlier, until the contractor has filed an initial patent application. Agencies, of course, retain the discretion to delay publication for additional periods of time.

(5) Nothing in this paragraph is intended to limit the authority of agencies provided in 35 U.S.C. 205 in circumstances not specifically described in this paragraph.

[52 FR 8554, Mar. 19, 1987, as amended at 60 FR 41812, Aug. 14, 1995]

§ 401.14 Standard patent rights clauses.

(a) The foll owing is the standard patent rights clause to be used as specified in § 401.3(a).

Patent Rights (Small Business Firms and Nonprofit Organizations)

(a) Definitions

(1) *"Invention"* means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

(2) *"Subject invention"* means any invention of the *contractor* conceived or first actually reduced to practice in the performance of work under this *contract,* provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of *contract* performance.

(3) *"Practical Application"* means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or government regulations, available to the public on reasonable terms.

(4) *"Made"* when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(5) *"Small Business Firm"* means a small business concern as defined at section 2 of Pub.L. 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this clause, the size standards for small business concerns involved in government procurement and subcontracting at 13 CFR 121.3-8 and 13 CFR 121.3-12, respectively, will be used.

(6) *"Nonprofit Organization"* means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c) and exempt from taxation under section 501(a) of the Internal Revenue Code (25 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

(b) Allocation of Principal Rights

(1) The *Contractor* may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause and 35 U.S.C. 203. With respect to any subject invention in which the *Contractor* retains title, the Federal government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.

(c) Invention disclosure, Election of Title and Filing of Patent Application by *Contractor*.

(1) The *contractor* will disclose each subject invention to the *Federal Agency* within two months after the inventor discloses it in writing to *contractor* personnel responsible for patent matters. The disclosure to the agency shall be in the form of a written report and shall identify the *contract* under which the invention was made and the inventor(s). It shall be sufficiently complete in

technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the *agency*, the *Contractor* will promptly notify the *agency* of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the *contractor.*

(2) The *Contractor* will elect in writing whether or not to retain title to any such invention by notifying the *Federal agency* within two years of disclosure to the Federal agency. However, in any case where publication, on sale or public use has initiated the one year statutory period wherein valid patent protection can still be obtained in the United States, the period for election of title may be shortened by the *agency* to a date that is no more than 60 days prior to the end of the statutory period.

(3) The *contractor* will file its initial patent application on a subject invention to which it elects to retain title within one year after election of title or, if earlier, prior to the end of any statutory period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use. The *contractor* will file patent applications in additional countries or international patent offices within either ten months of the corresponding initial patent application or six months from the date permission is granted by the Commissioner of Patents and Trademarks to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) Requests for extension of the time for disclosure, election, and filing under subparagraphs (1), (2), and (3) may, at the discretion of the agency, be granted.

(d) Conditions When the Government May Obtain Title

The *contractor* will convey to the *Federal agency,* upon written request, title to any subject invention—

(1) If the *contractor* fails to disclose or elect title to the subject invention within the times specified in (c), above, or elects not to retain title; provided that the *agency* may only request title within 60 days after learning of the failure of the *contractor* to disclose or elect within the specified times.

(2) In those countries in which the contractor fails to file patent applications within the times specified in (c) above; provided, however, that if the *contractor* has filed a patent application in a country after the times specified in (c) above, but prior to its receipt of the written request of the *Federal agency,* the *contractor* shall continue to retain title in that country.

(3) In any country in which the *contractor* decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention.

(e) Minimum Rights to *Contractor* and Protection of the *Contractor* Right to File

(1) The *contractor* will retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, except if the *contractor* fails to disclose the invention within the times specified in (c), above. The *contractor's* license extends to its domestic subsidiary and affiliates, if any, within the corporate structure of which the *contractor* is a party and includes the right to grant sublicenses of the same scope to the extent the *contractor* was legally obligated to do so at the time the *contract* was awarded. The license is transferable only with the approval of the Federal agency except when transferred to the successor of that party of the *contractor's* business to which the invention pertains.

(2) The *contractor's* domestic license may be revoked or modified by the funding *Federal agency* to the extent necessary to achieve expeditious practical application of the subject invention pursuant to an application for an exclusive license submitted in accordance with applicable provisions at 37 CFR Part 404 and agency licensing regulations (if any). This license will not be revoked in that field of use or the geographical areas in which the *contractor* has achieved practical application and continues to make the benefits of the invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of the funding *Federal agency* to the

extent the *contractor,* its licensees, or the domestic subsidiaries or affiliates have failed to achieve practical application in that foreign country.

(3) Before revocation or modification of the license, the funding *Federal agency* will furnish the *contractor* a written notice of its intention to revoke or modify the license, and the *contractor* will be allowed thirty days (or such other time as may be authorized by the funding *Federal agency* for good cause shown by the *contractor*) after the notice to show cause why the license should not be revoked or modified. The *contractor* has the right to appeal, in accordance with applicable regulations in 37 CFR Part 404 and agency regulations (if any) concerning the licensing of Government-owned inventions, any decision concerning the revocation or modification of the license.

(f) *Contractor* Action to Protect the Government's Interest

(1) The *contractor* agrees to execute or to have executed and promptly deliver to the *Federal agency* all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those subject inventions to which the *contractor* elects to retain title, and (ii) convey title to the *Federal agency* when requested under paragraph (d) above and to enable the government to obtain patent protection throughout the world in that subject invention.

(2) The *contractor* agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the *contractor* each subject invention made under *contract* in order that the *contractor* can comply with the disclosure provisions of paragraph (c), above, and to execute all papers necessary to file patent applications on subject inventions and to establish the government's rights in the subject inventions. This disclosure format should require, as a minimum, the information required by (c)(1), above. The *contractor* shall instruct such employees through employee agreements or other suitable educational programs on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The *contractor* will notify the *Federal agency* of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a

reexamination or opposition proceeding on a patent, in any country, not less than thirty days before the expiration of the response period required by the relevant patent office.

(4) The *contractor* agrees to include, within the specification of any United States patent applications and any patent issuing thereon covering a subject invention, the following statement, "This invention was made with government support under (identify the *contract*) awarded by (identify the Federal agency). The government has certain rights in the invention."

(g) Subcontracts

(1) The *contractor* will include this clause, suitably modified to identify the parties, in all subcontracts, regardless of tier, for experimental, developmental or research work to be performed by a small business firm or domestic nonprofit organization. The subcontractor will retain all rights provided for the *contractor* in this clause, and the *contractor* will not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(2) The *contractor* will include in all other subcontracts, regardless of tier, for experimental developmental or research work the patent rights clause required by *(cite section of agency implementing regulations or FAR).*

(3) In the case of subcontracts, at any tier, when the prime award with the Federal *agency* was a contract (but not a grant or cooperative agreement), the agency, subcontractor, and the contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the Federal agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (j) of this clause.

(h) Reporting on Utilization of Subject Inventions

The *Contractor* agrees to submit on request periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the *contractor* or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the *contractor,* and such other data and information as

the *agency* may reasonably specify. The *contractor* also agrees to provide additional reports as may be requested by the *agency* in connection with any march-in proceeding undertaken by the *agency* in accordance with paragraph (j) of this clause. As required by 35 U.S.C. 202(c)(5), the *agency* agrees it will not disclose such information to persons outside the government without permission of the *contractor.*

(i) Preference for United States Industry

Notwithstanding any other provision of this clause, the *contractor* agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any subject inventions in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the *Federal agency* upon a showing by the contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(j) March-in Rights

The *contractor* agrees that with respect to any subject invention in which it has acquired title, the *Federal agency* has the right in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the *agency* to require the *contractor,* an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the *contractor,* assignee, or exclusive licensee refuses such a request the *Federal agency* has the right to grant such a license itself if the Federal agency determines that:

(1) Such action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use.

(2) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee or their licensees;

(3) Such action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee or licensees; or

(4) Such action is necessary because the agreement required by paragraph (i) of this clause has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such agreement.

(k) Special Provisions for contracts with Nonprofit organizations

If the contractor is a nonprofit organization, it agrees that:

(1) Rights to a subject invention in the United States may not be assigned without the approval of the Federal agency, except where such assignment is made to an organization which has as one of its primary functions the management of inventions, provided that such assignee will be subject to the same provisions as the contractor;

(2) The contractor will share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (when the agency deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) The balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, will be utilized for the support of scientific research or education; and

(4) It will make efforts that are reasonable under the circumstances to attract licensees of subject invention that are small business firms and that it will give a preference to a small business firm when licensing a subject invention if the contractor determines that the small business firm has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that

are not small business firms; provided, that the contractor is also satisfied that the small business firm has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the contractor. However, the contractor agrees that the Secretary may review the contractor's licensing program and decisions regarding small business applicants, and the contractor will negotiate changes to its licensing policies, procedures, or practices with the Secretary when the Secretary's review discloses that the contractor could take reasonable steps to implement more effectively the requirements of this paragraph (k)(4).

(l) Communication

(Complete According to Instructions at 401.5(b))

(b) When the Department of Energy (DOE) determines to use alternative provisions under § 401.3(a)(4), the standard clause at § 401.14(a), above, shall be used with the following modifications unless a substitute clause is drafted by DOE:

(1) The title of the clause shall be changed to read as follows: *Patent Rights to Nonprofit DOE Facility Operators*

(2) Add an "(A)" after "(1)" in paragraph (c)(1) and add subparagraphs (B) and (C) to paragraph (c)(1) as follows:

(B) If the subject invention occurred under activities funded by the naval nuclear propulsion or weapons related programs of *DOE*, then the provisions of this subparagraph (c)(1)(B) will apply in lieu of paragraphs (c)(2) and (3). In such cases the contractor agrees to assign the government the entire right, title, and interest thereto throughout the world in and to the subject invention except to the extent that rights are retained by the contractor through a greater rights determination or under paragraph (e), below. The contractor, or an employee-inventor, with authorization of the contractor, may submit a request for greater rights at the time the invention is disclosed or within a reasonable time thereafter. *DOE* will process such a request in accordance with proce-

dures at 37 CFR 401.15. Each determination of greater rights will be subject to paragraphs (h)-(k) of this clause and such additional conditions, if any, deemed to be appropriate by the *Department of Energy.*

(C) At the time an invention is disclosed in accordance with (c)(1)(A) above, or within 90 days thereafter, the contractor will submit a written statement as to whether or not the invention occurred under a naval nuclear propulsion or weapons-related program of the *Department of Energy.* If this statement is not filed within this time, subparagraph (c)(1)(B) will apply in lieu of paragraphs (c)(2) and (3). The contractor statement will be deemed conclusive unless, within 60 days thereafter, the Contracting Officer disagrees in writing, in which case the determination of the Contracting Officer will be deemed conclusive unless the contractor files a claim under the Contract Disputes Act within 60 days after the Contracting Officer's determination. Pending resolution of the matter, the invention will be subject to subparagraph (c)(1)(B).

(3) Paragraph (k)(3) of the clause will be modified as prescribed at § 401.5(g).

(c) As prescribed in § 401.3, replace (b) of the basic clause with the following paragraphs (1) and (2):

(b) Allocation of principal rights. (1) The Contractor may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause, including (2) below, and 35 U.S.C. 203. With respect to any subject invention in which the Contractor retains title, the Federal Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world.

(2) If the Contractor performs services at a Government owned and operated laboratory or at a Government owned and contractor operated laboratory directed by the Government to fulfill the Government's obligations under a Cooperative Research and Development Agreement (CRADA) authorized by 15 U.S.C. 3710a, the Government may require the Contractor to negotiate an agreement with the CRADA collaborating party or parties regarding the allocation of rights to any subject invention the Contractor makes, solely or jointly, under

the CRADA. The agreement shall be negotiated prior to the Contractor undertaking the CRADA work or, with the permission of the Government, upon the identification of a subject invention. In the absence of such an agreement, the Contractor agrees to grant the collaborating party or parties an option for a license in its inventions of the same scope and terms set forth in the CRADA for inventions made by the Government.

[52 FR 8554, Mar. 19, 1987, as amended at 69 FR 17301, April2, 2004]

§401.15 Deferred determinations

(a) This section applies to requests for greater rights in subject inventions made by contractors when deferred determination provisions were included in the funding agreement because one of the exceptions at § 401.3(a) was applied, except that the Department of Energy is authorized to process deferred determinations either in accordance with its waiver regulations or this section. A contractor requesting greater rights should include with its request information on its plans and intentions to bring the invention to practical application. Within 90 days after receiving a request and supporting information, or sooner if a statutory bar to patenting is imminent, the agency should seek to make a determination. In any event, if a bar to patenting is imminent, unless the agency plans to file on its own, it shall authorize the contractor to file a patent application pending a determination by the agency. Such a filing shall normally be at the contractor's own risk and expense. However, if the agency subsequently refuses to allow the contractor to retain title and elects to proceed with the patent application under government ownership, it shall reimburse the contractor for the cost of preparing and filing the patent application.

(b) If the circumstances of concerns which originally led the agency to invoke an exception under § 401.3(a) are not applicable to the actual subject invention or are no longer valid because of subsequent events, the agency should allow the contractor to retain title to the invention on the same conditions as would have applied if the standard clause at § 401.14(a) had been used originally, unless it has been licensed.

(c) If paragraph (b) is not applicable the agency shall make its determination based on an assessment whether its own plans regarding the invention will better promote the

policies and objectives of 35 U.S.C. 200 than will contractor ownership of the invention. Moreover, if the agency is concerned only about specific uses or applications of the invention, it shall consider leaving title in the contractor with additional conditions imposed upon the contractor's use of the invention for such applications or with expanded government license rights in such applications.

(d) A determination not to allow the contractor to retain title to a subject invention or to restrict or condition its title with conditions differing from those in the clause at § 401.14(a), unless made by the head of the agency, shall be appealable by the contractor to an agency official at a level above the person who made the determination. This appeal shall be subject to the procedures applicable to appeals under § 401.11 of this part.

§ 401.16 Electronic filing.

Unless otherwise requested or directed by the agency,
The written report required in (c)(1) of the standard clause in § 401.14(a) may be electronically filed;

(a) The written election required in (c)(2) of the standard clause in § 401.14(a) may be electronically filed; and

(b) The close-out report in (f)(1) and the information identified in (f)(2) and (f)(3) of § 401.5 may be electronically filed.

[60 FR 41812, Aug. 14, 1995]

§401.17 Submissions and inquiries

60 FR 41812, Aug. 14, 1995]

The Patent Application Process Outside the United States

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As an intellectual property manager, one of your initial decisions when developing a patent-filing strategy for a new invention will be whether to pursue patent protection outside of the United States. In making this decision, you will likely be asked to consider and balance a number of different factors, including the commercial and marketing potential of the invention internationally, the cost of obtaining and maintaining patent rights in each country where protection is desired, and whether or not the invention is even patentable under applicable foreign patent laws. Although you, or your U.S. counsel, will typically engage the services of a patent attorney in each country where protection is sought, having a general understanding of foreign-filing procedures and laws will help you through the initial decision-making process regarding whether to file internationally, as well as enable you to more effectively manage the prosecution of each foreign case filed. Clearly, a complete summary of all relevant foreign procedures and laws is beyond the scope of this manual. Accordingly, the purpose of this chapter is not to set forth a step-by-step guide to obtaining foreign patent rights, but rather to provide a brief overview that can be used as a starting point as you begin to familiarize yourself with the patent application process outside of the United States. As such, this chapter should be viewed as a general reference tool and should not be relied upon as a substitute for legal advice. It is recommended that, prior to undertaking any patent-filing strategy, you should seek the advice of professional counsel.

Filing Decision

Once the decision has been made to file for patent protection outside of the United States, you will need to decide where (namely, in what countries) patent protection will be pursued, as well as when and how to file patent applications in those countries.

Where?

Deciding whether to pursue patent protection in a particular country is often a business decision based upon (a) the perceived commercial value of the invention in the country and (b) the cost of obtaining patent rights to the invention in the country. For example, if three countries together comprise 60 percent of the worldwide market for an invention, it is likely that you will want to file an application in each country. On the other hand, if prosecution in all three countries is anticipated to cost $30,000 over the next three years and you only have a budget of $5,000 per year, then you may be forced to forego prosecution in at least one country.

Although such business considerations will likely guide your decision-making process, it is also wise to determine whether the invention is even patentable in the countries under consideration. For example, certain types of subject matter, such as business methods, that are patentable in the United States are not patentable in all countries. In addition, as discussed further in "National Examination Process," many of the requirements for patentability, such as novelty and written description, differ from country to country and may preclude you from obtaining patent protection in a particular country.

When?

Generally speaking, you should decide whether to pursue patent protection outside of the United States no later than twelve months from the filing date of your original U.S. patent application (nonprovisional or provisional). If filed within this twelve-month window, most corresponding foreign applications can be filed with a claim to priority back to your original U.S. filing date. Similar to related U.S. applications, if such a claim to priority is made, the effective filing date for prior-art purposes of the foreign patent application will be the same as your original U.S. filing date, in other words, the foreign application will be treated as if it was filed on the same day as the original U.S. application for prior-art purposes.

In most cases, a claim to priority in a foreign application will be made under the Paris Convention. The Paris Convention is a treaty that allows applicants to file an initial patent application in any country that is a member of the Paris Convention and then to file

subsequent applications to the same invention in other member countries within a specified period of time. For utility patent applications, this time period is twelve months from the original filing date. Most industrialized countries have joined the Paris Convention. However, Taiwan remains a notable exception. More information regarding the Paris Convention, including a complete listing of the contracting states, can be found on the World Intellectual Property Organization's Web site at http://www.wipo.int/treaties/en/.

Whether an application filed in a non-Paris Convention country may claim priority to an earlier filed U.S. application will depend on the patent laws of that country. For example, under the patent laws of Taiwan, which has not joined the Paris Convention, priority may be claimed to an application filed up to twelve months before in a country that is either a member of the World Trade Organization or that allows Taiwan nationals to claim priority based on reciprocity. More information regarding Taiwan's patent laws can be found on the Taiwan Intellectual Property Office's Web site at http://www.tipo.gov.tw/eng/laws/laws.asp#1.

How?

In addition to determining in which countries you wish to pursue patent protection, you will also need to decide how to file your application in each of the selected countries. There are three different routes for filing internationally, namely, (1) filing separate applications in each country directly, (2) filing applications in regional patent offices (*e.g.,* European Patent Office, African Intellectual Property Organization, African Regional Industrial Property Organization, and Eurasian Patent Convention), and (3) filing an international patent application under the Patent Cooperation Treaty. There are pros and cons associated with each of these methods. However, many applicants choose to file an international patent application in order to preserve their rights to subsequently pursue protection in a number of different foreign countries without immediately incurring the costs associated with multiple national filings.

National Filing

The process of prosecuting a foreign national application is, in many respects, similar to the process for a U.S. application. First, you, or your U.S. counsel, will need to prepare

and file, with the assistance of a foreign patent attorney, an application that meets the requirements prescribed by the patent laws of the country in which you are filing. Typically, your initial U.S. application can be used with minor variations. Following filing, the patent office of the country will consider your application and may issue one or more official actions, similar to the office actions you receive from the U.S. Patent and Trademark Office (USPTO), regarding the patentability of your invention. Finally, if your application is allowed (and following an opposition period in certain countries), you will receive a patent granting you rights in the country of filing. A few of the differences between foreign and U.S. prosecution processes include the annual annuity payments charged by many foreign jurisdictions for pending and issued cases and the option of deferring examination for a number of years following the filing of an application.

Regional Filing

If you chose to file an application in one of the regional patent offices noted above, then upon issuance of your patent, you will have the option to register that patent in one or more of the countries that are members of that regional office to obtain patent rights in those countries. For example, if you file an application in the European Patent Office (EPO), then, upon issuance, you may, subject to certain limitations, register your patent (and obtain rights) in any of the member states, such as France, Germany, and the United Kingdom. A complete listing of the EPO member states is available on the EPO's Web site at http://www.european-patent-office.org/epo/members.htm. It is important to note that, upon filing your European application, you will need to designate all the countries in which you will want to register your patent. If you fail to designate a particular country, you will not be able to register your European patent in that nation.

Patent Cooperation Treaty Filing

The Patent Cooperation Treaty, known as the PCT, is a treaty that provides for the filing of a single international patent application that can subsequently be converted into multiple foreign national applications up to thirty (and in some cases thirty-one) months from the filing date or, if applicable, the priority date of the PCT application. Your PCT application may claim priority under the Paris Convention back to a U.S. application filed within the preceding twelve months and any national or regional applications resulting from your

PCT application will also be entitled to this priority claim. Most of the major countries of the world are PCT members, and all PCT members are bound by the Paris Convention. A complete list of the PCT contracting states can be found on the World Intellectual Property Organization's Web site at http://www.wipo.int/treaties/en/.

The Patent Cooperation Treaty provides for two phases of international examination of a PCT application known as Chapter I and Chapter II. As discussed in more detail below, the Chapter I stage involves the filing and initial processing of the application, as well as the issuance of an international search report and written opinion, while the Chapter II stage provides for further substantive examination. Note that, in general, the decision of the examiner during international examination is not binding on the national patent offices of the countries into which the international application is converted, nor does a PCT application mature into an international patent. However, since many national patent offices will use the international examiner's decision as a starting point, and, consequently, issue any claims deemed allowable during international examination, many applicants find it advantageous to resolve as many issues as possible during the PCT process.

Pros and Cons

The first two of the above options, namely, filing multiple national and regional applications, are typically employed when either (1) the decision has been made to only pursue patent protection in several countries or (2) patent protection is desired in a country that is not a party to the PCT. In addition, you may be able to obtain foreign patent rights more quickly through direct national and regional filings since the intermediate steps associated with an international PCT application will be skipped. As noted above, a disadvantage to filing multiple applications directly in numerous national and regional patent offices is that the individual national filing fees, foreign attorney fees, translation fees, annuity fees, and prosecution fees will be incurred earlier than if a single international PCT application is filed. Furthermore, since the patent offices of many countries will defer to the decision of the examiner in an international PCT application, obtaining a favorable international examination report may help to reduce national and regional prosecution costs after conversion.

Another benefit to filing a PCT application is that you preserve your right to pursue protection in a number of different foreign countries without making a final decision regarding where applications will actually be filed. This allows you to collect additional information regarding the value and patentability of the invention in various countries and may be particularly appealing when dealing with inventions having long periods of research and development prior to commercialization.

PCT Application Process

Since the filing of an international PCT application is frequently the filing approach agreed upon to obtain foreign patent rights, the following is a brief summary of the PCT application process under the current PCT regulations (which became effective January 1, 2004, and apply to PCT applications having international filing dates on or after that date). For your reference, a timeline of the process is included in the appendix. In addition, further details regarding the PCT application process may be found on the World Intellectual Property Organization's Web site at http://www.wipo.int/pct/en/. Note that the PCT application process is different for PCT applications filed prior to January 1, 2004, so if you are handling the prosecution of such an application, you will need to seek advice regarding the prior PCT regulations.

Chapter I

Filing

Chapter I of the PCT application process is commenced by filing an international PCT application with one of the PCT receiving offices. For U.S. applicants, filing will occur with either the U.S. receiving office or the international bureau (IB) of the World Intellectual Property Organization (WIPO) in Geneva. The filing of a PCT application is treated as the filing of separate patent applications in each PCT member country designated in the PCT application. Under the current PCT regulations, all PCT member countries are automatically designated upon filing. However, an applicant has the option to exclude countries with self-designation laws (*i.e.*, countries in which a corresponding national application would be deemed withdrawn as a result of a PCT designation), such as Germany, the Republic of Korea, and the Russian Federation.

International Search Report and Written Opinion

Approximately sixteen months from the earliest priority date claimed in a PCT application, the applicable international searching authority (ISA) will prepare and mail to the applicant an international search report (ISR) and a written opinion (ISA-WO) regarding the patentability of the pending claims. If desired, in most cases, U.S. applicants may choose to have the EPO serve as the ISA rather than the USPTO. In preparing the ISR and ISA-WO, the ISA will conduct a prior-art search and review any patents and publications that are identified and considered relevant. The ISA-WO is intended to provide a preliminary opinion on novelty, inventive step, and industrial applicability, as well as point out any objections to the form or clarity of the claims. Claim amendments may be submitted to the IB in response under Article 19 of the PCT, however, such amendments will not be substantively considered by either the ISA or IB during international examination.

Publication

Eighteen months from the earliest priority date claimed in a PCT application, the application will be published along with the ISR and any Article 19 amendments. The ISA-WO will not be published at this time and will not become publicly available through the IB prior to the expiration of thirty months from the earliest priority date claimed in the PCT application.

Chapter I International Preliminary Report on Patentability

If a PCT application does not enter the Chapter II stage of international examination, then the IB will issue a Chapter I international preliminary report on patentability (IPRP [Ch. I]) regarding the patentability of the pending claims. The IPRP (Ch. I) will have the same content as the ISA and ISA-WO and will not take into account any Article 19 amendments filed. Note that, under the Chapter I process, an applicant may also submit further informal comments on the ISA-WO to the IB prior to issuance of the IPRP (Ch. I). Such comments will be made available to the patent office of each designated country along with the IPRP (Ch. I), but will not be considered by the IB when preparing the IPRP (Ch. I).

National Conversion

Originally, an applicant had to decide at nineteen months from the earliest priority date claimed in a PCT application whether to (1) convert such international application into a national application in any of the designated member countries or (2) enter the Chapter II stage of international examination. However, in April 2002, the deadline for national conversion of a PCT application under Chapter I was extended to thirty (and in some cases thirty-one) months from the earliest priority date. Although most PCT member states have now adopted this extended deadline, there remain a handful of countries in which an applicant must still choose at nineteen months between national conversion and Chapter II examination (although these countries may still be entered through regional conversion).

Chapter II

Demand for International Preliminary Examination

At the later of twenty-two months from the earliest priority date claimed in a PCT application or three months from the date the ISR and ISR-WO for the application are issued under Chapter I, Chapter II of the PCT application process may be commenced by filing a demand for international preliminary examination. Note that, upon the initiation of Chapter II, all *designated* countries will become *elected* countries, and the patent offices of such countries will subsequently be referred to as *elected patent offices.* Since the deadline for national conversion under the Chapter I process has been extended to thirty months from the priority date as noted above, Chapter II is now largely an optional stage in the PCT application process. However, unlike Chapter I, the Chapter II process does allow for a dialogue between the applicant and the international examiner on issues related to patentability and may be favored if a negative ISA-WO was received during Chapter I examination.

If a demand for international preliminary examination is filed, the ISA-WO will be treated as the initial written opinion by the international preliminary examining authority (IPEA). In order to allow sufficient time to have amendments and/or comments filed in response to this initial written opinion considered by the IPEA, such amendments and/or com-

ments should be filed simultaneously with the demand. Informal comments submitted during the Chapter I process will not be considered by the IPEA, however, Article 19 amendments may be considered upon request by an applicant.

Chapter II International Preliminary Report on Patentability

Approximately twenty-eight months from the earliest priority date claimed in a PCT application under Chapter II international examination, the IPEA will issue a Chapter II international preliminary report on patentability (IPRP [Ch. II]) regarding the patentability of the pending claims. Similar to the ISA-WO, the IPRP (Ch. II) is intended to provide an opinion on novelty, inventive step, and industrial applicability, as well as point out any objections to the form or clarity of the claims.

The IPRP (Ch. II) will be made available to each elected patent office and will be made publicly available to third parties by the IB after the expiration of thirty months from the earliest priority date claimed in the PCT application. However, it is possible that the prosecution history of a PCT application in Chapter II may become publicly available earlier through the elected patent offices. For example, if the EPO acts as the IPEA for a particular PCT application, then, at any time following publication of such application, the EPO will permit public inspection of the file. Accordingly, if maintaining the confidentiality of the prosecution for a particular PCT application is critical, you will need to consider more thoroughly these disclosure laws and may want to consider using the USPTO as the IPEA.

National Conversion

Under the Chapter II process, an applicant must decide at thirty (or in some cases thirty-one) months from the earliest priority date claimed in a PCT application whether to convert such international application into a national application in any of the elected member countries.

National Examination Process

Regardless of how you initially file your patent application internationally, namely, via separate national or regional applications, a single international PCT application, or a combination thereof, your application will eventually enter the national examination process in the countries (or regions) in which patent protection is desired. This national examination process is typically the most complex and expensive part of obtaining foreign patent rights. As an intellectual property manager, you will need to work with foreign patent counsel to manage the prosecution of each foreign case filed and ensure that the various prosecution strategies pursued in each jurisdiction are consistent. Initially, you will find yourself relying quite heavily on the advice of your foreign patent counsel. However, as you become more familiar with foreign patent laws, you should be able to take a more proactive role in the process.

As mentioned at the beginning of this chapter, many of the requirements for patentability differ from country to country and may preclude you from obtaining patent protection in a particular nation. Perhaps one of the best introductory examples to this variability in laws is a study of how the requirements for novelty differ among the United States, Europe, and Japan.

Absolute vs. Relative Novelty

The United States has what is commonly referred to as a *relative novelty* requirement, whereas, both Europe and Japan have variations on what is commonly referred to as an *absolute novelty* requirement. Broadly speaking, *absolute novelty* holds that an invention is not novel if it was described in print or made known in any way in any country prior to the filing or priority date of the application directed to such invention. Relative novelty, on the other hand, further holds that there are certain limitations to the nature, place, and/or time of prior publications and uses that will be destructive of novelty. For example, under U.S. law, a prior publication may be considered an invalidating reference regardless of where such publication occurred, whereas a prior use is only invalidating if it occurred in the United States.

European Absolute Novelty

Under Article 54 of the European Patent Convention (EPC), an invention is considered to be novel if it does not form part of the state of the art, which is defined as "everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application."[1] In other words, under European law, the state of the art comprises all information for which there is the theoretical possibility of at least one person having access to the information. For example, a prior unprinted specification laid open to public inspection in any country will be destructive of novelty. Furthermore, a single sale to a single customer anywhere in the world will render the invention available to the public.

However, even this European absolute novelty standard has some exceptions. For example, if information is disclosed under a confidentiality obligation, then it is not considered to form part of the state of the art. Furthermore, Article 55 of the EPC provides that information disclosed no more than six months prior to the filing of the European patent application will not be destructive of novelty if such information is disclosed (1) by an applicant at certain international exhibitions (*i.e.,* exhibitions that meet the criteria set forth in EPC Article 55) or (2) by a third party against the will of the applicant (for example, in violation of a confidentiality obligation).[2]

For your reference, the full text of the European Patent Convention is available on the EPO's Web site at http://www.european-patent-office.org/legal/epc/index.html.

Japanese Absolute Novelty

Section 29 of the Japan Patent Law (JPL) provides that an invention is considered to be novel if the invention was not (1) publicly known in Japan or elsewhere prior to the filing of the patent application therefore, (2) publicly worked in Japan or elsewhere prior to the filing of the patent application therefore, or (3) described in a distributed publication or made available to the public through electric telecommunication lines in Japan or elsewhere prior to the filing of the patent application therefore.[3] Similar to the definition of the state of the art under European laws, Section 29 of the JPL places relatively few limitations on the nature, place, and/or time of prior knowledge, uses, and publications that will be considered destructive of novelty.

However, again similar to Europe, there are exceptions to the Japanese standard of absolute novelty. For example, if information is disclosed under a confidentiality obligation, then such information is not considered to be publicly known, worked, or available. Furthermore, Section 30 of the JPL provides that an invention that was publicly known, worked, or available for no more than six months prior to the filing of the Japanese patent application will not be destructive of novelty if such invention was known, worked, or available due to (1) an experimental use by the inventor, (2) a printed publication or disclosure through electric telecommunication lines by the inventor, (3) a presentation at one of the scientific organizations designated by the Japanese Patent Office (JPO) by the inventor, (4) an act by a third party against the will of the applicant, (5) a presentation at an officially recognized exhibition.[4] Note that the foregoing exceptions under Japanese law are broader than those under European law. In particular, Japanese law provides a six-month grace period for experimental uses and publications by the inventor.

For your reference, the full text of the JPL is available on the JPO's Web site at http://www.jpo.go.jp/shoukaie/patent.htm.

U.S. Relative Novelty

As you know, under U.S. patent law, a person shall be entitled to a patent unless (1) the invention was known or used by others in this country or patented or described in a printed publication in this or a foreign country before the invention thereof by the applicant, or (2) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.[5] For simplicity, this section will only discuss 35 USC §102(a) and §102(b). Note that some foreign jurisdictions also have laws similar to, for example, 35 USC §102(e), and your foreign patent counsel should advise you regarding the same.

As an initial matter, note that the critical date when determining whether a reference is destructive of novelty in the U.S. is typically the date of invention. However, the filing date may be used as the critical date in certain limited situations (*i.e.*, the statutory bar provisions of 35 USC §102[b]). Throughout the remainder of the world, as seen above with respect to Europe and Japan, the critical date is the filing date.

The relative novelty standard of 35 USC §102(a) places a number of limitations on the nature, place, and/or time of prior knowledge, uses, and sales that will be considered destructive of novelty. For example, as noted previously, a prior publication may be considered an invalidating reference regardless of where such publication occurred, whereas a prior use is only invalidating if it occurred in the United States. Although 35 USC §102(b) may appear to be analogous to EPC Article 55 and JPL Section 30, the provisions of §102(b) may be viewed as expanding, rather than limiting, the scope of what may qualify as anticipatory prior art. For example, under §102(a), an invention published in the U.S. two years prior to the filing date of the U.S. application will not be considered an invalidating reference so long as the publication did not occur prior to the invention by the applicant. However, such publication will be considered a bar to patentability under §102(b) since the U.S. application was filed more than one year after the publication.

As a final matter, similar to European and Japanese laws, there are further exceptions to the U.S. relative novelty standard. For example, exceptions are provided for secret knowledge and uses, as well as certain public experimental uses. However, it is important to note that all sales will be considered destructive of novelty, regardless of whether they occur in secret (*e.g.,* under a confidentiality agreement).

Comparative Examples

To further illustrate the differences between the U.S., European, and Japanese standards for novelty, consider the following examples.

Prior Art	Anticipatory Reference (yes/no)		
	United States	Europe	Japan
Journal article by inventor > one year prior to filing date	Yes	Yes	Yes
Journal article by inventor seven months prior to filing date	No	Yes	Yes
Journal article by inventor one month prior to filing date	No	Yes	No
Sale by inventor in U.S. > one year prior to filing date	Yes	Yes	Yes
Sale by inventor in U.S. > one year prior to filing date under confidentiality	Yes	No	No
Sale by inventor in Canada > one year prior to filing date	No	Yes	Yes
Experimental use by inventor in U.S. > one year prior to filing date	No	Yes	Yes
Experimental use by inventor in U.S. five months prior to filing date	No	Yes	No
Experimental use by inventor in U.S. five months prior to filing date under confidentiality	No	No	No

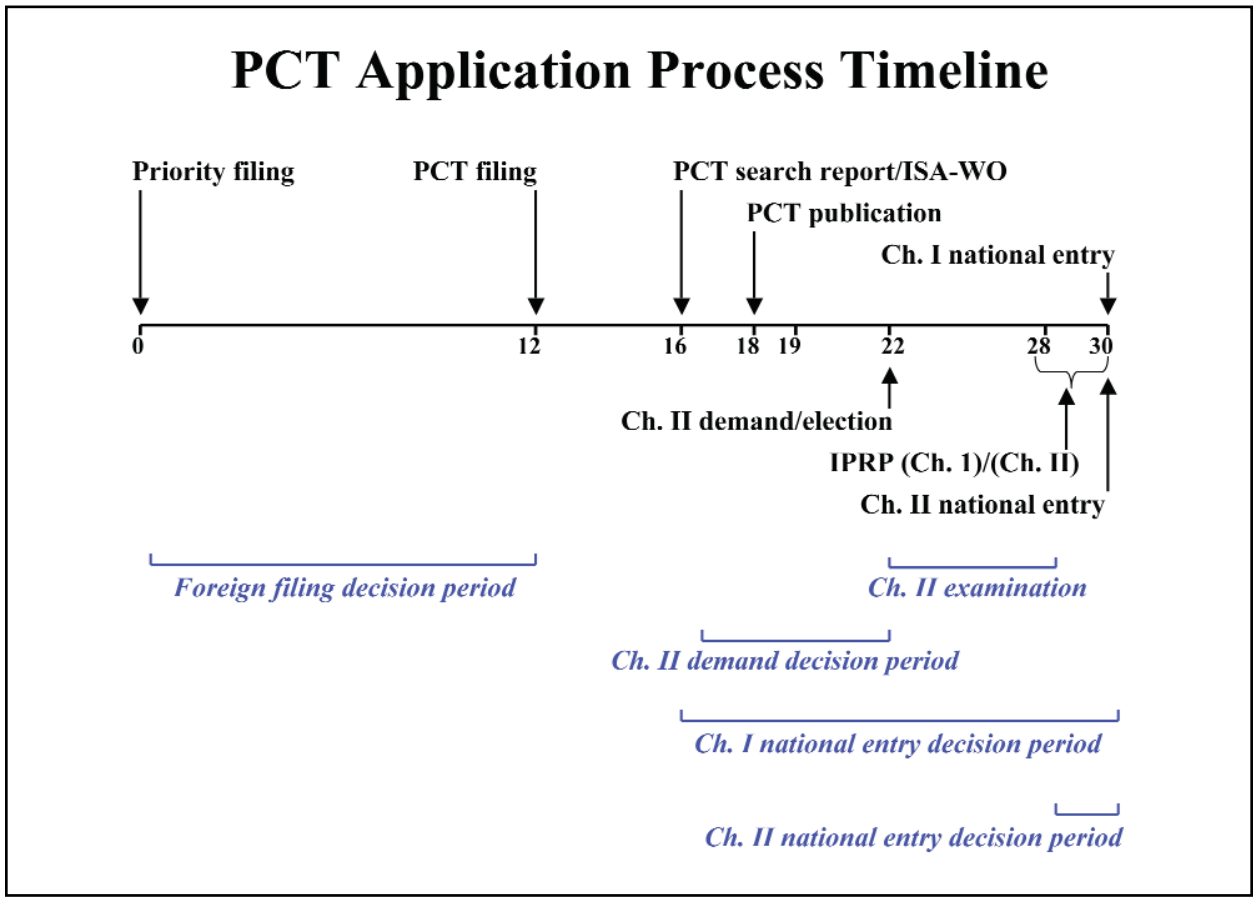
Conclusion

As you can see, obtaining patent rights outside of the United States is a complex process involving numerous foreign procedures and laws. Hopefully, this chapter provided you with a basic framework that you can use to orient yourself as you learn further details about the international patent application process.

Notes

1. European Patent Convention, Article 54(2).
2. European Patent Convention, Article 55(1).
3. Japan Patent Law, Article 29(1).
4. Japan Patent Law, Article 30.
5. 35 USC §102(a) and §102(b).

Appendix



Copyright Protection

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Overview

Copyright law grants the copyright owner certain exclusive rights. When creating multimedia works, the copyright in each element must be considered: Software, music, and images used for a multimedia work may be separately owned. The copyright owner is generally the author or the author's employer. Formal copyright registration is not required for protection, but registration does result in enhanced rights.

Copyright protection does not extend to scientific or historic facts. In light of the limited copyright protection for databases, database owners often seek protection either under trade secret law, by limiting access to specific inquiries (e.g., Lexis and Westlaw), or under contract, by limiting use, or disclosure.[1] Computer software may be protected by copyright, trade secret, or patent law.

The Copyright Owner's Rights

The Statutory Exclusive Rights

The Constitution grants Congress the power "to promote the progress of science and useful arts, by securing for limited times to authors . . . the exclusive right to their respective writings. . . ."[2] Copyright protection applies to any "original works of authorship fixed in a tangible medium of expression."[3]

As determined in *Feist Publications Inc. v Rural Telephone Service Co Inc.,* "Original, as the term is used in copyright, means only that the work was independently created by the author . . . and that it possesses at least some minimal degree of creativity."

The copyright owner has the exclusive right to (1) reproduce the work, (2) prepare derivative works, (3) distribute copies to the public, (4) perform the work publicly, and

(5) display the work publicly.[4] The author of certain works of visual art also has rights of attribution and integrity.[5] Copyright protection will not extend to "any idea, procedure, process, system, method of operation, concept, principle, or discovery regardless of the form in which it is described, explained, illustrated, or embodied."[6]

Copyright protection is available for a wide range of works, including books; plays; software; music and lyrics; artwork (pictorial, graphic, or sculptural); motion pictures; and architectural works.[7]

Protection for Derivative Works

A derivative work "is work based upon one or more preexisting works . . . . A work consisting of editorial revisions, annotations, elaborations, or other modifications which, as a whole, represents an original work of authorship....".[8] Thus, a movie based upon a book is a derivative work.

The subject matter of copyright as specified by § 102 includes compilations and derivative works, but protection for work employing preexisting material in which copyright subsists does not extend to any part of the work to which such material has been used unlawfully.

The copyright in a compilation or derivative work extends only to the material contributed by the author of such work, as distinguished from the preexisting material employed in the work, and does not imply any exclusive right in the preexisting material. The copyright in such work is independent of, and does not affect or enlarge the scope, duration, ownership, or subsistence of, any copyright protection in the preexisting material.

Recasting, transforming, or adapting the original work creates derivative works.[9] The derivative work must at least reflect "a minimal degree of creativity," but even a slight amount will suffice.[10] "Intermediate copies" used in software development or database creation may be infringing derivative works.[11]

In *Micro Star v. Formgen,* the court held that user-generated levels of the Duke Nuken 3D computer game created by the Build Editor software included with the game "substantially

incorporate protected material from the preexisting work." By using the preexisting source art files and MAP files, the user-generated levels qualified as derivative works. The defendant was precluded from commercially distributing those derivative works.

The author of the original work retains the copyright for the original work; however, if creation of a derivative work has been authorized, the second author owns the copyright on all new material contributed by the second author.[12] The United States has not recognized moral rights in literary works; therefore, "once authorship rights are relinquished through a work-for-hire contract provision, the right to attribution is also relinquished unless that right is reserved explicitly in the contract."[13]

A licensee is not ordinarily authorized to prepare derivative works.[14] The Ninth Circuit has held that liability for unauthorized creation of a derivative work does not require proof that the derivative work is independently copyrightable.[15] Substantial similarity of the derivative work to the original work must be shown to prove infringement.[16]

Protection for Compilations

Copyright Law

A compilation is material "selected, coordinated, or arranged" to constitute "an original work of authorship."[17] In general, for a compilation to be protected by copyright, it must meet the following three requirements: (1) the collection and assembly of preexisting data; (2) the selection, coordination, or arrangement of that data; and (3) a resulting work that is original, by virtue of the selection, coordination, or arrangement of the data contained in the work.[18]

Copyright protection can extend to the selection and arrangement of unprotected components.[19] A compilation of less than four selections is presumed to lack authorship.[20] Copyright protection for a data compilation is thin and does not protect purely factual material. Protection requires creativity and originality in the selection or arrangement of facts.

Also determined in Feist, "A factual compilation is eligible for copyright if it features an original selection or arrangement of facts, but the copyright is limited to the particular selection or arrangement."

A "mechanical or routine" selection process lacks sufficient creativity to be copyrighted.[21] "All facts-scientific, historical, biographical and news of the day . . . are part of the public domain and available to every person." Copyright law permits the use of such facts to create another compilation "that differs in more than a trivial degree."[22]

In *CDN v. Kapes,* the defendant used a computer program to generate retail prices of coins on an Internet Web site. The data was derived from plaintiff's Web site price lists. The prices on plaintiff's list are original creations compiling data "chosen and verified with creativity and judgment." Therefore, the defendant infringed plaintiff's compilation.

Frequently, copyright protection has not prevented copying from databases.[23] To enhance protection, authors of computerized data services and related materials (e.g. CD-ROMs) should consider enhancing copyright protection of their product by including creative material and organization. Factual data should be supplemented with descriptive or normative terms.[24]

Proposed Database Protection Legislation

In light of the limited copyright protection, developers have attempted to protect databases either under trade secret law, by limiting access to specific inquiries (e.g., Lexis and Westlaw), and under contract, by limiting use or disclosure.[25] Lexis and Westlaw protect their databases using both methods. Interest remains, however, in securing a stronger form of legal protection for compilations of data.

In March 1996, the European Union issued its Directive on Legal Protection of Databases.[26] The European directive provides protection for databases for a fifteen-year term.[27] The European directive, however, grants protection to foreign nationals only to the extent the foreign nation grants comparable protection.[28] Because the United States currently does not grant comparable protection, U.S. firms will be unable to protect their

databases under the European directive. This problem is one reason an international treaty on protection of databases was proposed to the World Intellectual Property Organization (WIPO). WIPO did not consider or adopt a proposed database treaty in 1996.

Database protection legislation comparable to the EU sui genesis protection has been proposed in Congress, but has never been successful.[29] Alternative legislation that would allow the FTC to enforce database protection under circumstances similar to the hot news misappropriation doctrine has also been proposed.[30] Neither bill has been enacted into law.[31]

Electronic Publishing

In *New York Times Co. v. Tasini,* a group of freelance writers sued the *New York Times* and Mead Data Central Corp. for publishing their work electronically. The issue presented was whether articles written for the *New York Times, Sports Illustrated*, and other publishers could be republished on electronic databases (like Lexis/Nexis) and on CD-ROMs.

The district court judge held that republication did not violate the copyright of the freelance authors because the publisher had a limited statutory privilege to produce revisions of the published "collective works."[32] This precedent, however, did not authorize republication as content for a Web site or a separate electronic publication.

The Second Circuit reversed, holding that the authors had not authorized electronic republication and that the Copyright Act provision on collective works did not authorize these electronic republications.[33] The electronic publication loses the selection, coordination, and arrangement that constitutes the publisher's copyrightable contribution to the compilation. The copyright in preexisting material contributed by the freelance author continues to belong to the individual authors.[34]

The Supreme Court affirmed the Second Circuit opinion. Several class actions pending in the Southern District of New York were awaiting disposition of *Tasini.*[35]

Authors are already attempting to renegotiate their contracts to clarify electronic republication rights. Anyone licensing content from third parties should include specific provisions addressing any desired rights of electronic publication. A class action against the *Boston Globe, New York Times, Wall Street Journal,* and others alleged the new contract language constitutes an unfair and deceptive trade practice and recently was settled for up to $18 million.[36]

The American Society of Journalists and Authors' Guild founded the Authors' Registry as a licensing clearinghouse (similar to ASCAP or BMI in the music industry). The National Writers' Union has launched a similar registry (The Publications Rights Clearinghouse). Information about electronic publishing is available at the American Society of Journalists and Authors Web site at http//www.asja.org.

Similar issues arise regarding electronic use of photographic images. The Eleventh Circuit has held that republication of photographs in a CD-ROM compilation by *National Geographic* violates the rights of the freelance photographers.[37] Again reversing a trial court decision in favor of the publishers, the appellate court found that the CD-ROM was a new collective work, not a mere revision of the previously published collective work.

Authorship

Creation

Ownership of a copyright "vests initially in the author or authors of the work." 17 U.S.C. § 201(a). The author must "actually create the work" transforming an abstract idea "into a fixed, tangible expression." *Community for Creative Non-Violence v. Reid,* 490 U.S. 730, 737 (1989); 17 U.S.C. § 102(a).

Work for Hire

Work Created by an Employee

If material is created by an employee within the scope of his employment, then the Copyright Act presumes the employer owns the copyright as a work made for hire. "In the case of a work made for hire, the employer or other person for whom the work was

prepared is considered the author . . . and, unless the parties have expressly agreed otherwise in a written instrument signed by them, owns all of the rights comprised in the copyright." 17 U.S.C. § 201(b).[38]

Specially Commissioned Work

Even if the work is not prepared by an employee it may be a work for hire if (1) it is specially ordered or commissioned for use as a contribution to a collective work, a part of a motion picture or other audiovisual work, a translation, a supplementary work, a compilation, an instructional text a test, answer material for a test, or an atlas; and (2) the parties expressly agree in a written instrument signed by them that the work shall be considered a work made for hire.[39] This provision cannot apply to work already existing before the agreement to create a work for hire in the listed categories. The parties must agree prior to creation of a specially commissioned work that it will be a work for hire.[40] However, the actual writing memorializing the agreement may be executed after creation of the work.[41]

Software only rarely qualifies as one of these specially commissioned categories. Therefore, use of consultants rather than salaried employees to develop software and multimedia works raises questions of copyright ownership. In the absence of an employment relationship, the copyright usually is owned by the consultant, not the development company. Software created by an independent contractor rarely qualifies as a work for hire.[42]

Web site content may qualify as a specially commissioned collective work, audiovisual work, or compilation.

Who is an Employee?

In *Community for Creative Non-Violence v. Reid,* 490 U.S. 730 (1989), the United States Supreme Court held that the common law rules of agency determine whether an author is an employee for purposes of copyright ownership. "In determining whether a hired party is an employee under the general common law of agency, we consider the hiring party's right to control the manner and means by which the product is accomplished. Among the other factors relevant to this inquiry are the skill required; the source

of the instrumentalities and tools; the location of the work; the duration of the relationship between the parties; whether the hiring party has the right to assign additional projects to the hired party; the extent of the hired party's discretion over when and how long to work; the method of payment; the hired party's role in hiring and paying assistants; whether the work is part of the regular business of the hiring party; whether the hiring party is in business; the provision of employee benefits; and the tax treatment of the hired party. See Restatement § 220(2) (setting forth a nonexhaustive list of factors relevant to determining whether a hired party is an employee). No one of these factors is determinative." 490 U.S. at 751-52 (footnotes omitted).

In *Aymes v. Bonelli,* 980 F.2d 857, 862-63 (2d Cir. 1992), the court held that the programmer owned the copyright in software because the "employer" paid no insurance benefits or payroll taxes and withheld no state or federal taxes. Other cases have considered additional factors in reaching inconclusive results.[43]

What Is the Scope of Employment?

Courts have relied on the *Restatement (Second) of Agency,* § 228 (1958) to determine if conduct was "within the scope of employment." Under the *Restatement,* conduct within the scope of employment: (1) is of the kind of work the employee was hired to perform, (2) occurs substantially within authorized work hours, and (3) is actuated, at least in part, by a desire to serve the employer.[44]

In *Miller v. CP Chemicals, Inc.,* 808 F. Supp. 1238, 1243-44 (D. S.C. 1992), certain computer programs created by a full-time employee at home on his own time (and without any overtime compensation) were used to make the quality control laboratory, which the employee supervised, more efficient. The court held the programs were created within the scope of employment; therefore, the employer owned the copyright. Other cases, however, have recognized that software created after hours as a hobby may be owned by the employee.[45]

If the work fails to qualify as a work for hire, the "employer" must assert either joint authorship or an assignment of rights.

Duration and Termination of Copyright for Works for Hire

Duration

The duration of copyright under the Copyright Act of 1976 as amended in 1998, depends on the nature of the work:

- *Works by single author:* Generally, copyright duration for works by a single author is the life of the author plus 70 years. 17 U.S.C. § 302(a).
- *Joint works:* Copyright endures for a term consisting of life of the last surviving author plus 70 years. 17 U.S.C. § 302(b).
- *Works for hire:* The duration of copyright for a work for hire is 95 years from the date of publication or 120 years from the date of creation, whichever expires first. 17 U.S.C. § 302(c). Congress has both extended the term of registration[46] and restored certain works unprotected due to copyright formalities.[47]

Termination

The 1976 Copyright Act provides for the right of an author or an author's heirs to terminate a transfer, license, or grant of the copyright in the author's work.[48] Approximately thirty-five years from the date of publication of the work or forty years from the license or transfer of the copyright in the work, the author or the author's successor (generally the spouse or children and grandchildren) can undo the license or transfer.[49] The right to terminate is nonassignable, and termination is not waivable in advance. This termination provision arose from Congress's recognition of the generally unequal bargaining power between an author and the "buyers" of the author's works.

Works for hire are explicitly excluded from this termination provision.[50] The purpose of narrowly defining works for hire is to protect creators of works from the unfair bargaining power of those parties who commission their works. By specifically excluding all but a few categories of works from being considered works for hire, most creators retain termination rights. This provides the creator an opportunity to renegotiate the bargain and share in any windfall of an unexpectedly successful work through termination. Because the termination provision is for the protection of authors, it cannot be waved in advance.[51] If a work does not qualify as a work for hire, parties may not negotiate that the work is "for hire" to avoid the termination provisions.[52]

Application to Universities

An employee must produce a written agreement signed by both parties to rebut the presumption that materials created in the course of employment are works for hire.[53] A policy manual utilized by Parkland College was held insufficient to change the statutory presumption because it was not signed.[54] Cases dealing with photographs taken by university employees hold the university retained ownership of the copyright under the work-for-hire doctrine.[55]

Traditionally, universities and colleges have made no claim to copyrights in scholarly works. The leading case is *Weinstein v. University of Illinois,* 811 F.2d 1091 (7th Cir. 1987), which clarified that "The statute is general enough to make every academic article a 'work for hire' and therefore vest exclusive control in universities rather than scholars. ...The University of Illinois, like many other academic institutions...adopt[ed] a policy defining 'work for hire' for purposes of its employees, including its professors. According to the policy, which is part of each professor's contract with the University, a professor retains the copyright [subject to certain exceptions]". 811 F.2d at 1094.

Further, "The University concedes in this court that a professor of mathematics who proves a new theorem in the course of his employment will own the copyright to his article containing that proof. This has been the academic tradition since copyright law began....when Saul Bellow, a professor at the University of Chicago, writes a novel, he may keep the royalties."[56]

While all courts may not recognize a scholarly work exception to the work-for-hire doctrine, copyright ownership for articles written by faculty members is generally not claimed by the university. If copyright ownership in a scholarly work was asserted by the university, the application of the work-for-hire doctrine as set forth in the statute (which makes no reference to the scholarly-work exception) would raise difficult legal and "political" issues. Analysis of the interplay between university policies on copyright ownership and the Copyright Act has been the subject of several law review articles.[57]

Regulations applicable to any government agency providing funding for the development of copyrighted works must be construed in a manner consistent with the Copyright Act.[58]

Joint Authorship

The authors of a joint work are co-owners of copyright in the work.[59]

A joint work is a work prepared by two or more authors with the intention that their contributions be merged to inseparable or interdependent parts of a unitary whole.[60]

Under the test formulated by professor Goldstein: A collaborative contribution will not produce a joint work, and a contribution will not obtain a co-ownership interest, unless the contribution represents original expression that could stand on its own as the subject matter of copyright.[61]

Each joint author can use the work and separately exercise his or her exclusive right as author (subject to an accounting for the resulting profits).[62] In contrast, joint owners of a patent may make, use, sell, offer for sale, or import without the consent of the joint owner and without any duty to account.[63]

Making a substantial and valuable contribution to the work (even if the contribution is copyrightable) is not enough to create joint authorship. To determine who is an author, the court must consider (1) creative control exercised, (2) objective manifestations of intent to be co-authors, and (3) audience appeal created by both contributions.[64] A claim of co-ownership must be brought within a three-year statute of limitations.[65]

Transfers

Assignment (Ownership)

Any transfer of copyright ownership must be written.[66] Whether a transfer agreement that does not mention "copyright" satisfies the writing requirement is an issue of interpretation.[67]

An exclusive license is treated as a transfer of ownership. The owner of an exclusive license has the right to bring a copyright action.[68] Copyright law does not permit an exclusive licensee to transfer its rights without the consent of a licensor.[69] The licensor generally retains all rights not specifically granted.[70]

Any of the copyright owners' exclusive rights can be separately assigned (or licensed).[71] Care must be exercised to retain the rights necessary to exploit the work. For example, where one party has the right to reproduce and another party has the right to distribute, both parties must cooperate or "effectively be put out of business."[72] Some cases have suggested a license that does not state a duration has a minimum term of thirty-five years (the period prior to the termination right under 17 U.S.C. § 203).[73]

License (Rights)

The writing requirement only applies to an exclusive license.[74] A nonexclusive license may be oral or implied from the parties' conduct.[75] Copying or distributing outside the scope of the license granted is not only a breach of contract but copyright infringement.[76]

Some users of Internet materials assume there is an implied license to use material posted on the Internet. The existence and scope of any implied license has not been tested by the courts. The limited case law does not support an implied license for commercial use.

In *Microstar v. Formgen Inc.,* 942 F. Supp. 1312 (S.D. Cal. 1996), aff'd in part, 154 F.2d 1107 (9th Cir. 1998), the developer of the Duke Nukem 3D game permitted players to create new game levels using an editor provided by the developer. The court held the developer had no copyright in the user-created levels (which had been posted on the Internet) but could prevent commercial distribution of new levels (unauthorized derivative works). The court refused to imply a license allowing commercial use of these derivative works.[77] "Courts have found implied licenses only in 'narrow' circumstances where one party 'created a work at [the other's] request and handed it over, intending that [the other] copy and distribute it.'"[78]

The safest course would be to require assignment from all persons working on material that you expect to own. An express written assignment can eliminate considerable uncertainty.[79] Although ancillary issues may arise with regard to termination rights in the future (generally thirty-five years after the publication or registration of the work),[80] the written assignment can confirm ownership of the right to exploit the work and to exclude others from doing so.

Registration

For works created since January 1, 1978, formal registration of a copyrighted work is not mandatory. Works created prior to January 1, 1978, but protected by common law copyright, continue to be eligible for common law protection.[81]

Registration allows the recovery of statutory damages and attorneys' fees if infringement is shown.[82] Moreover, registration is required prior to commencement of a copyright infringement action.[83] A copyright owner can obtain an expedited registration and sue for actual damages if the infringement commences before the work was registered.

Generally, registration is still preferred for published works. The registration fee must be accompanied by the appropriate form and a copy of the work to be registered.[84] The copyright registration must disclose all preexisting works upon which the registered work is based, the identity of the author, and the dates of creation and publication. In litigation to enforce the copyright, defendants will often assert fraud on the copyright office based upon inaccuracies in the registration. Generally, these defects will not invalidate the registration in the absence of intent to conceal material facts from the copyright office.[85] The preferred solution, however, is to file an accurate application for registration.

Registration within five years of publication creates a presumption of ownership and validity.[86] A copyright registration extends to copyrightable elements contributed by the author.[87] There may be no presumption of copyright validity if an owner of computer software files a massive source code as a single collection and fails to identify the original portions of the work.[88]

The Copyright Act sets forth eight separate categories of works eligible for copyright protection.[89] The Register of Copyrights is authorized to allocate works to administrative classes by regulation.[90] "This administrative classification of works has no significance with respect to the subject matter of copyright or the exclusive rights provided by this Title."[91] Consequently, erroneously classifying the work in the application for registration should not invalidate the copyright registration.[92]

Copyright Infringement

The elements of a prima facie case for copyright infringement are (1) ownership of a valid copyright and (2) copying of protected expression. *Feist Publications, Inc. v. Rural Telephone Service Co., Inc.,* 499 U.S. 340, 361 (1991). Copyright ownership is usually established by proving registration.[93] Copying can be inferred through circumstantial evidence of access, if the programs are "substantially similar."[94] In the case of a computer program, substantial similarity must be determined from the perspective of the intended users of the program.[95] Unauthorized copying constitutes copyright infringement subject to civil and criminal liability.[96] There is no liability, however, if the work is not copied but, instead, independently created.[97]

Direct Infringement

Violating or authorizing violation of any of the exclusive statutory exclusive rights without permission of the copyright owner constitutes infringement. Copyright protection extends not only to the text of a literary work but to nonliteral elements as well.

Direct infringement does not require intent or any particular state of mind.[98]

Protection extends to unauthorized paraphrasing that uses nonliteral elements of the original expression, as evidenced in *Nichols v. Universal Pictures Corp.,* "It is of course essential to any protection of literary property . . . that the right cannot be limited literally to the text, else a plagiarist would escape by immaterial variations." Nichols v. Universal Pictures Corp., 45 F.2d 119, 121 (2d Cir. 1930) (L. Hand, J.), cert. denied, 282 U.S. 902 (1931) (protection extends to plot and characters). For example, the "unique setting, characters, plot, and sequence of events" in a book cannot be copied in a motion picture.[99]

Copyright protection extends only to the expression employed, not the ideas of the work.[100] Common ideas cannot be protected "otherwise, the first to come up with an idea will corner the market."[101]

Apple defined the proper analysis of copyright disputes in the Ninth Circuit:

- The plaintiff must identify the *source(s)* of the alleged similarity between his work and the defendant's work.

- *Using analytic dissection,* and if necessary, expert testimony, *the court must determine whether any of the allegedly similar features are protected by copyright...* [U]nprotectable ideas must be separated from potentially protectable expression; to that expression, the court must then apply the relevant limiting doctrines in the context of the particular medium involved, through the eyes of the ordinary consumer of that product
- Having dissected the alleged similarities and considered the range of possible expression, the court must define the scope of the plaintiff's copyright-that is, protection. Depending on the degree of protection, *the court must set the appropriate standard for a subjective comparison of the works* to determine whether, as a whole, they are sufficiently similar to support a finding of illicit copying.

Apple Computer, Inc. v. Microsoft, Corp., 35 F.3d 1435, 1443 (9th Cir. 1994) (emphasis added). Only after these three steps may the works be subjectively compared by the jury. Analytic dissection is used to determine if the features the plaintiff wants to protect are copyrightable.[102] Analytic dissection examines the concrete elements of both works (utilizing a list of "criteria of comparison" such as plot, themes, dialogue, mood, setting, pace, sequence of events, and characters).[103]

Copyright protection can also extend to the selection and arrangement of unprotected components.[104] A protected work can consist entirely of standard features which, viewed in their entirety, are creatively arranged. Such an arrangement, however, is entitled only to "thin" copyright protection. For works consisting largely of unprotectable elements infringement should not be found absent "bodily appropriation of expression," by "copying or unauthorized use of substantially the entire item."[105] "Having correctly found that almost all the similarities spring ... from basic ideas and their obvious expression, [the court] correctly concluded that illicit copying could occur only if the works as a whole are virtually identical."[106]

The effect of the Ninth Circuit's opinion in Apple is to narrow the copyright protection afforded audiovisual works (and, by implication, literary works) implemented through computer software. When design decisions are dictated by choices among a limited number

of efficient techniques for implementing the desired function, those design decisions may not be protected by copyright unless the infringer creates a virtually identical product.

Indirect Infringement

An employee is ordinarily jointly and severally liable with his employer for any exercise of authority that infringes the owner's exclusive rights.[107] A party not engaged in direct infringement may be liable for vicarious or contributory infringement.[108]

Vicarious Liability

If a defendant has the right and ability to supervise the infringer and a direct financial interest in the infringement, then that defendant may be liable for vicarious infringement even without actual knowledge that the copyright was being infringed.[109] "When an individual seeks to profit from an enterprise in which identifiable types of losses are expected to occur, it is ordinarily fair and reasonable to place responsibility for those losses on the person who profits, even if that person makes arrangements for others to perform the acts that foreseeably cause the losses." *Polygram International Publishing, Inc. v. Nevada/TIG, Inc.,* 855 F. Supp. 1314, 1325 (Mass. 1994). The COMDEX trade show organizer, which rented booths to exhibitors, was subject to vicarious liability where the organizer exercised authority and control over exhibitors and profited not only from renting booth space but also from charging admission fees to view the exhibits.[110]

Contributory Infringement

If a defendant is in a position to control use of the copyrighted work and knowingly induces, causes, or materially contributes to use of the copyrighted work without permission of the copyright owner, then the defendant may be liable for contributory infringement.[111]

Several cases have held a bulletin board service (BBS) operator liable for copyright infringement by users.[112] The availability of relief against an access provider (e.g., Compuserv, America Online), however, remains uncertain. Merely linking to a site containing infringing material has been held not to constitute contributory infringement.[113]

A service provider could be liable for contributory infringement if it failed to prevent known copyright violations.[114] Recent controversies have required the courts to apply copyright law to Internet use and peer-to-peer file-transfer technologies. See, e.g., *A&M Records, Inc. v. Napster, Inc.,* 239 F.3d 1004 (9th Cir. 2001) (peer-to-peer transmission of digital audio files likely to support claims for a direct infringement, contributory infringement and vicarious infringement); *Metro Goldwin Mayer Studios, Inc. v. Grokster, Ltd.,* 380 F.3d 1154 (9th Cir. 2004) (no vicarious or contributory liability).

In *Napster,* the court found that the defendant had both (1) actual knowledge that its system was used to infringe copyright protection and (2) the ability to block system access for suppliers of infringing material.[115] The court also found vicarious liability because Napster had the right and ability to supervise conduct by its users and failed to exercise that right.[116]

In Grokster, the court held that the defendant software distributor did not have knowledge of infringement by users and did not have the right and ability to supervise users. Because the software had significant non-infringing uses, the plaintiffs were required to show knowledge of specific infringement by the defendant.[117] Although the plaintiffs provided notice of infringement, the notice arrived "when defendants do nothing to facilitate, and cannot do anything to stop, the alleged infringement."[118] The court distinguished the *Napster* case based on the underlying technology.

"The software at issue in Napster I and Napster II employed a centralized set of servers that maintained an index of available files. In contrast, under ... Grokster's quasi-decentralized, supernode, KaZaa-type network, no central index is maintained. Indeed, at present, neither Streamcast nor Grokster maintains control over index files. As the District Court observed, even if the software distributors 'closed their doors and deactivated all computers within their control, users of their products could continue sharing files with little or no interruption.'"[119]

Vicarious liability was also unavailable because "it does not appear from any of the evidence in the record that either of the defendants has the ability to block access to indi-

vidual users."[120] "This sort of monitoring and supervisory relationship that has support vicarious liability in the past is completely absent in this case."[121] [*Grokster* was reversed on appeal as this edition went to press. 125 S.Ct. 2764 (2005). In *Grokster,* the Supreme Court found contributory infringement could arise where the P2P service is promoted for the purpose of infringing copyright "as shown by clear expression or other affirmative steps taken to foster infringement." Liability for contributory infringement is possible if Grokster intentionally induced or encouraged infringement. Liability is premised "on purposeful, culpable expression and conduct...." The liability, however, is limited. For example, "mere knowledge of infringing potential or of actual infringing uses would not be enough here to subject a distributor to liability." Similarly, Grokster would not be subject to liability for acts such as providing technical support or product updates to customers.

The extent of vicarious liability or contributory liability has been tested by cases seeking to impose liability on credit card companies,[122] age-verification services,[123] and investors.[124]

Liability for Internet-related activities must also consider the impact of the Digital Millennium Copyright Act (DMCA). The provisions of DMCA are discussed later in this chapter. Relief has been obtained under DMCA, for example, to prevent distribution of software to decrypt movies contained on digital versatile disks (DVDs).[125]

Criminal Liability

Since 1992, felony penalties may apply to infringement of any copyrighted work (including software) if the infringer acts "willfully and for purposes of commercial advantage or private financial gain."[126] The penalty for felony copyright infringement is imprisonment for not more than five years or a fine of not more than $250,000, or both if, during a six-month period, the infringer copies at least ten works with a retail value of more than $2,500.[127]

Congress continues to expand the criminal penalties for copyright infringement. The No Electronic Theft (NET) Act (PL 105-147) (111 Stat. 2678) eliminated the requirement of commercial advantage or private financial gain to allow prosecution of bulletin board operators who willfully copy and distribute works worth more than $1,000.[128] Civil and criminal copyright infringement sanctions can be substantial.[129]

Damages

For infringement commencing after registration, the owner can recover statutory damages (up to $150,000 per work for willful infringement) and attorney fees.[130] For any infringement, the owner can recover actual damages (measured by the owner's loss or the infringer's gain).[131]

Defenses[132]

Sovereign Immunity

States are given immunity from suits filed in federal court by the 11th Amendment to the U.S. Constitution: "The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State."

Congress sought to abrogate states' immunity from suit in adopting the 1992 Copyright Remedy Clarification Act. Congress did not have that power. States, and state institutions, may not be subject to suit unless they have consented to be sued.[133]

Fair Use

Statutory Protection

Use of copyrighted material will not constitute infringement if it is within the scope of the statutory fair use defense.[134] Four factors are to be considered in determining whether use of a copyrighted work for comment, scholarship, research, and other purposes is a permissible fair use: (1) the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes; (2) the nature of the copyrighted work; (3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and (4) the effect of the use upon the potential market for or value of the copyrighted work.

17 U.S.C. § 107. The extent to which the use "transforms" the original work weighs in favor of a finding of fair use.[135]

In *Sony Computer Entertainment Inc. v. Connectix Corp.,* 203 F.3d 596 (9th Cir. 2000), cert. denied, 121 S.Ct. 172 (2000), the Ninth Circuit held that intermediate copying of the Sony PlayStation operating system was a fair use. The defendant reverse engineered a compatible system. The distribution of a resulting commercial product to run PlayStation games on Macintosh computers did not preclude a finding of fair use. The final product did not contain any Sony code and the copying was necessary to analyze functional (unprotected) aspects of the software. The court found the process was "modestly transformative" and led to the development of "entirely new object code."

In *Kelly v. Arriba Soft Corp.,* 77 F. Supp. 2d 1116 (CD Cal. 1999), aff'd in part, 336 F.3d 811 (9th Cir. 2003), the court held access to plaintiff's copyrighted photographs through an Internet search engine for images was fair use. Display of the full-sized images, however, violated the exclusive right to display the works.[136]

In *Ticketmaster Corp. v. Tickets.com, Inc.,* 2000 WL 1887522 (C.D. Cal. August 10, 2000), the fair use doctrine prevented issuance of a preliminary injunction based on copyright claims to bar defendant's collection of data from plaintiff's database.[137] Copying a compilation merely to extract factual data may be fair use.[138]

To the extent there is a reasonable licensing procedure available, copying without a readily available license will be deemed to weigh against a finding of fair use. See *American Geophysical Union v. Texaco, Inc.,* 37 F.3d 881 (2nd Cir. 1994). Texaco was held liable to publishers of scientific and technical journals for making unauthorized copies for use by Texaco scientists. Texaco permitted its scientists and engineers to photocopy articles from numerous scientific and technical journals to which Texaco subscribed. The court held that this use of the copyrighted material infringed on the exclusive rights of the copyright holder. Texaco later agreed to pay a retroactive licensing fee to the Copyright Clearance Center (CCC).[139]

Authorization to photocopy journals may be obtained through the CCC, a nonprofit clearinghouse established in 1977 that collects a fee for blanket permission to photocopy copyrighted materials registered with CCC. CCC provides two principal services. The

transactional-reporting service requires the user to report the copying and pay a fee printed on the first page of each article. Alternatively, the annual authorization service determines an annual fee based on a survey of photocopying use. Licensing programs are also available at UMI Article Clearing House for printed material and through BMI and ASCAP for music.

Educational Use

Classroom Copying Guidelines

In 1976, an "Agreement on Guidelines for Classroom Copying in Not for Profit Educational Institutions with Respect to Books and Periodicals" was included in the legislative history of the Copyright Act.[140] The guidelines, although not legally binding, were intended to describe a safe harbor for certain copying for educational purposes. In general, a teacher can make single copies for personal use, scholarly research, or class preparation of a chapter in a book, an article in a periodical, a short story or poem, and certain charts, diagrams, cartoons, and pictures. Multiple copies can be made for use in the classroom if each copy includes a notice of copyright and meets the guideline requirements for (1) brevity, (2) spontaneity, and (3) cumulative effect.

The brevity provisions are self-explanatory. The spontaneity provision requires that the use be inspired by the individual teacher at a time when it would be unreasonable to expect a response to a request for permission in time for "maximum teaching effectiveness." The cumulative-effect provisions limit use of the material to "one course in the school" not more than nine times during the class term, and of only limited materials from the same author, collective work, or periodical volume. The copying cannot be "repeated with respect to the same item by the same teacher from term to term." Nor can copying be "directed by higher authority."

Similar guidelines were published in the legislative history for educational uses of music: "Guidelines for Educational Uses of Music;"[141] thereafter, "Guidelines on Off-Air Recoding of Broadcast Programming for Educational Purposes" were promulgated in 1978.[142]

More recently, a Conference on Fair Use (CONFU)[143] led to another nonlegislative report on fair use guidelines for digital images, distance learning, and multimedia. The CONFU report endorsed the guidelines for digital images created by the Consortium of College and University Media Centers and sent to Congress on September 27, 1996.[144] Again, these guidelines are not legally binding. The guidelines proposed that images generally can be digitized unless they are readily available for purchase or license at a fair price. The guidelines for educational multimedia would allow students and educators to use copyrighted works in educational multimedia projects, subject to time, portion copying, and distribution limitations.

The CONFU interim report also included a statement on library uses of computer programs presented as a series of examples of uses of computer programs and multimedia works.

Performance and Display Exemption and the TEACH Act

The Copyright Act permits students and instructors to perform or display certain copyrighted materials in a classroom "or similar place devoted to instruction." 17 U.S.C. § 110. The distance-learning guidelines expand the circumstances under which copyrighted works may be performed and displayed for distance learning. The statute and the guidelines, however, do not permit the creation of individual copies for students. The guidelines do not apply to asynchronous delivery of distance learning over computer networks.

Congress directed the Copyright Office to consult with affected parties and make recommendations on how to promote distance education through digital technologies in Section 403 of DMCA. The Copyright Office report recommended amendments to 17 U.S.C. § 110(2) and 112 (permitting instructional Internet broadcasting). These recommendations were subsequently embodied in the Technology Education and Copyright Harmonization Act (TEACH) of 2002. TEACH permits "mediated instructional activities" by nonprofit educational institutions for distance learning.

The TEACH Act allows performance or display of copyrighted material "as a regular part of the systematic mediated instructional activities of ... an accredited non-profit educational institution."[145] The activities permitted must be "an integral part of the class experience"

controlled or supervised by the instructor.[146] The amount of material used and the type of use must be comparable to use in a live classroom setting.[147] The institution may transmit these materials if (1) technological measures are used to (a) limit transmission to enrolled students and (b) prevent retention or unauthorized dissemination and (2) copyright policies and informational materials are provided. Certain works can be converted to digital format for instructional purposes. The TEACH Act does not apply to works produced or marketed primarily for transmission via digital networks for mediated instructional activities. These provisions do not encompass textbooks, course packs, or other materials typically purchased and retained by students.[148]

Reproduction by Libraries and Archives

The Copyright Act permits certain copying by libraries and archives. 17 U.S.C. § 108. Again, guidelines were included in the legislative history of the Copyright Act in 1976.[149] This guideline is referred to as the "rule of five" (in any year a single entity can receive up to five articles published in the last five years from the same periodical). The library must also post a copyright warning set forth in 37CFR § 201.14.

First-Sale Doctrine

The Copyright Act distinguishes between the copyright and the physical copy.[150] The first-sale doctrine prevents a copyright owner from interfering with the subsequent use of copies sold.[151] Software is generally licensed for use and not sold and, therefore, is not subject to the first-sale doctrine.[152] If the only authorized chain of distribution is by license, purchase from a licensee does not constitute a first sale.[153]

Public Domain

When the owner's right to exclude others from using intellectual property is extinguished for any reason, that intellectual property is said to pass into the public domain and it can be used by anyone. Copyright protection does not extend to portions of a work which incorporate preexisting works either copyrighted by others or in the public domain.[154]

Copyright law will not bar access to factual data in the public domain.[155] Shareware, however, is not necessarily in the public domain.[156] The open source model uses a combination of contract and copyright protection to prevent works from entering the public domain while also preventing the full exercise of exclusive rights under copyright laws.[157]

Merger

Elements of a work which "must necessarily be used as incident to" the idea, process or system which is the subject of the work are not copyrightable.[158] This concept has developed into the doctrine of merger—an idea which can be expressed in only one way is said to have merged with the expression so as to be inseparable. Copyright will not bar copying that expression.[159]

In *Apple Computer, Inc. v. Microsoft Corp.,* the court concluded that "if the idea and the author's particular way of expressing that idea cannot be separated, under the concept of merger only identical copying of the expression is barred."[160]

A software developer was unable to prevent publication of tables generated by the software.[161] The software displays the Torah in a matrix so that characters can be extracted from the text. The court held that identifying the characters to form new words is an idea and that the plaintiff's software (and other software programs) are not original and are not protectable under the merger doctrine. The analysis can only be expressed in one of two ways (a linear or matrix format). "To grant protection to plaintiff for devising a formula capable of displaying Bible code finds in such a manner would grant plaintiff a monopoly over the unprotectable idea of a Bible code."[162]

Scenes á Faire

Copyright protection does not extend to features required by external factors or to achieve compatibility.[163] The scenes á faire doctrine bars protection.[164] Under the scenes á faire doctrine, stereotyped expression and standard or common features are excluded from copyright protection in the absence of a virtually identical copy. In Apple, the court noted scenes á faire and the merger doctrine are "barely distinguishable from one another."[165]

Method of Operation

A number of cases have held that functional aspects of computer software (as distinguished from expressive aspects implementing the software's function) are not eligible for copyright protection. In *Lotus Development Corp. v. Borland International, Inc.*, 49 F.3d 807 (1st Cir. 1995), aff'd, 116 S.Ct. 804 (1996), the appellate court held that Borland International did not infringe the copyright on the Lotus 1-2-3 spreadsheet program, even though Borland conceded it had included "a virtually identical copy of the entire 1-2-3 menu tree" in its Quattro and Quattro Pro 1.0 programs. The Borland Lotus Simulation Interface copied "the words and structure of Lotus' menu command hierarchy" so Borland users could execute macros written for Lotus 1-2-3 without rewriting the macros or learning a new command structure.

Copyright protection does not extend to any "procedure, process, system, [or] method of operation."[166] The appellate court held that the Lotus menu command hierarchy constitutes a "method of operation," analogous to the buttons used to operate a VCR machine. "The fact that there may be many different ways to operate a computer program, or even many different ways to operate a computer program using a set of hierarchically arranged command terms, does not make the actual method of operation chosen copyrightable; it still functions as a method for operating the computer and as such is uncopyrightable."[167]

This holding limits copyright protection for software.[168]

The Massachusetts District Court recently applied the methods of operation analysis in holding that copyright protection does not apply to enhancement software used to implement "company wide business practices." *ILOG Inc. v. Bell Logic LLC,* 181 F. Supp. 2d 3 (D. Mass. 2002). By copying the rule editors used in the original software, the enhancement merely copied a method of operation that is outside the scope of copyright protection. The elements that were allegedly copied (context sensitive pop-up menus, different commands and editors for technical users and business users, and color-coding key words, for example) were mere ideas that were implemented in the enhancement software without copying the original software code.

Individually, the elements are noncopyrightable ideas. In the aggregate, the elements constitute a method of operation. Either way, Bell Logic is not entitled to copyright protection.[169]

Misuse

Several recent cases have found a copyright holder's competitive misuse of the copyright to be a defense to copyright infringement.[170] In *Lasercomb America Inc.* v. *Reynolds,* "Lasercomb undoubtedly has the right to protect against copying of the Interact code. Its standard licensing agreement, however, goes much further and essentially attempts to suppress any attempt by the licensee to independently implement the idea that Interact expresses. The agreement forbids the licensee to develop or assist in developing any kind of computer-assisted die-making software...Lasercomb is attempting to use its copyright in a manner adverse to the public policy embodied in copyright law..."[171]

The defense of copyright misuse also has been held to preclude preliminary injunctive relief.[172]

The Digital Millennium Copyright Act

Civil Liability for Circumvention

The Statutory Framework

In October 1998, the Digital Millennium Copyright Act added Chapter 12 "Copyright Protection and Management Systems" to the Copyright Act. The prohibition against circumventing technological measures to control access to a work took effect two years after enactment (October 2000).[173] Although codified in the Copyright Act, DMCA is a separate statutory framework, independent of copyright law. DMCA technically does not define *copyright infringement.* Instead, DMCA creates liability in "a niche distinct from copyright infringment."[174]

Chapter 12 prohibits manufacturing or trafficking in any technology, product, service, or device primarily designed for the purpose of circumventing (1) a technological measure to control access to a protected work (i.e., descrambling a scrambled work, decrypting an

encrypted work)[175] or (2) the protection afforded by a technological measure for a right of copyright owner.[176] Opponents argued the provision against circumventing copy protection would limit fair use and prevent access to material not protected by copyright. A variety of exemptions to the prohibition on circumventing technological measures are contained in the statute.

In addition, the act provides that no person shall provide false copyright management information[177] or intentionally remove or alter any copyright management information.[178] Copyright management information includes the title and other information identifying the work; the name and other identifying information about the author, the copyright owner, or the performer; the terms and conditions for use of the work or such other information as the Register of Copyrights may prescribe by regulation.[179] Copyright management information does not include "any personally identifying information about a user."[180] Certain exemptions are discussed below.

Exemptions

- *Fair use:* Civil libertarians have argued that DMCA goes too far in protecting the rights of copyright owners.[181] The fair use defense (17 U.S.C. § 107) applies only to copyright infringement, not violations of DMCA anticircumvention provisions.[182] "Legal downstream use of the copyrighted material by customers is not a defense to the software manufacturers violation of § 1201(b)(1)."[183]
- *DMCA rulemaking:* The prohibition on circumventing technological measures to control access to a work does not apply to users likely to be adversely affected in their ability to make non-infringing uses of particular classes of copyrighted works (as determined by Library of Congress regulations).[184] This provision is intended to preserve the fair use exemption under existing copyright law. The factors identified in conducting rule making include the impact on "criticism, comment, news reporting, teaching, scholarship or research" and "the effect on the market for or value of copyrighted works."[185] These factors are similar to the fair use factors.[186]

Libraries and universities have provided comments on classes of works eligible for this exemption to the Librarian of Congress. The American Library Association is concerned

technological measures may be used "to change the way information is marketed and ... paid for." Pay-per-use technologies might unduly inhibit fair use.

Outside the recognized exemptions, circumvention of access control measures exposes the user to infringement liability.[187]

Acquisitions by Libraries

Nonprofit libraries, archives, and educational institutions are also exempt from liability for gaining access to a commercially exploited work "solely in order to make a good faith determination of whether to acquire a copy of that work for the sole purpose of engaging in conduct permitted under this title ...."[188] This exemption does not apply unless a copy "is not reasonably available in another form."[189] Willful violations for purposes of commercial advantage or financial gain can subject the library, archive, or educational institution to civil remedies, and repeated offenses can result in forfeiture of the exemption.[190] This exemption does not apply to trafficking in technology primarily designed to circumvent: (1) a technological measure to effectively control access to a work or (2) a protection afforded by such a technological measure to a copyright owner's rights.[191]

Additional statutory exemptions that may apply to software development include circumventing measures to control access to program elements for the sole purpose of identifying and analyzing those elements necessary to achieve interoperability of an independently created computer program,[192] encryption research,[193] and security testing.[194]

Damages

For violations of the provisions regarding copyright protection systems and copyright management information, a court may award injunctive relief, impoundment of devices involved in the violation, damages, and reasonable attorneys' fees.[195] Damages may constitute actual damages (including profits of the violator attributable to the violation) or statutory damages.[196] Statutory damages for circumventing copyright protection systems may range from $200 to $2,500 per act of circumvention.[197] Statutory damages regarding copyright management information can range from $2,500 to $25,000.[198] In the event the violation occurs within three years after a final judgment for "another such violation," the court may award damages of "up to triple the amount that would otherwise be awarded."[199]

The court may reduce or remit damages if "the violator was not aware and had no reason to believe that its acts constituted a violation."[200] Remission is mandatory if the foregoing provision applies to a nonprofit library, archive, or educational institution.[201]

Criminal Liability

A violation of the provisions regarding copyright protection systems or copyright management information, if willful and for purposes of commercial advantage or private financial gain, shall result in a fine of not more than $500,000 or imprisonment for not more than five years for a first offense.[202] Those penalties are doubled for any subsequent offense. The criminal sanctions do not apply to a nonprofit library, archive, or educational institution. A criminal proceeding must be commenced within five years after the cause of action arose.[203]

Litigation

Video Cases

Litigation involving the technological protection against copying and management systems has resulted from Web site distribution of software cracking the proprietary Contents Scrambling System (CSS) protection scheme for DVDs. Suit was filed in the Southern District of New York by Universal City Studies and others to obtain injunctive relief preventing distribution of software disabling the anticopying features for DVDs. A preliminary injunction was granted holding the DeCSS software violates 17 U.S.C. § 1201(a)(2) and must be removed from Internet Web sites. The statutory exemption provisions provide an exception for reverse engineering software, but not circumvention of technological copy protection schemes.[204] Unreported suits have been brought against iCraveTV (settled February 2000), ReplayTV, and RecordTV (settled April 2001).

In February 2004, the Northern District of California enjoined 321 Studios from selling a program that permits copying of DVDs. *321 Studios v. Metro Goldwyn Mayor Studios,* 307 F. Supp. 2d 1085 (N.D. Cal. 2004). The company sought a declaratory judgment that fair use permitted sale of its DVD X-Copy Software. The DVD X-Copy Software has two features intended to restrict unlawful uses: once the DVD is made, the hard drive is

erased and the DVD is encrypted so that it cannot be copied again. These features did not satisfy the court that 321 Studios complied with DMCA.

Audio Cases

The digital distribution of music in MP3 format was initially challenged by the Recording Industry Association of America in a suit to halt distribution of the Rio player.[205] The Ninth Circuit held the Rio was not subject to the royalty provisions of the Audio Home Recording Act as a digital audio recording device.[206]

Unable to obtain royalties from the Rio manufacturers, RIAA sought to prevent distribution of the digital content under copyright law. In December 1999, RIAA sued Napster claiming the software company had developed a program that lets online users trade unauthorized music files. Many universities, including University of Chicago and University of Texas, banned use of Napster to download music. In some campus networks, as much as 60 percent of traffic was reportedly attributable to use of Napster technology to reproduce audio files. Napster claimed more than 40 million users. Peer-to-peer distribution of copyrighted material was held not to meet the safe harbors available under DMCA.[207]

The district court granted an injunction, subsequently modified following appeal. *A&M Records, Inc. v. Napster, Inc.,* 114 F. Supp. 2d 896 (N.D. Cal. 2000), *aff'd in part,* 239 F.3d 1004 (9th Cir. 2001), *on remand,* 2001 WL 227083 (N.D. Cal. March 5, 2001) (Judge Patel ordered Napster to remove songs identified by the plaintiffs within three days), *aff'd,* 284 F.3d 1091 (9th Cir. 2002). A similar result protecting copyright owners was reached against a CD locker service offered by MP3.com.[208] MP3.com subsequently settled with some plaintiffs. By March 2001, MP3.com had reportedly paid $160 million.[209]

Suits were also filed against Scour, Aimster, MusicCity, Kazaa, Morpheus, and Grokster on behalf of publishers of music, movies, and software.[210] Aimster encrypted its service in an unsuccessful effort to use DMCA to its advantage. See *In re Aimster,* 252 F. Supp. 2d 634 (N D Ill. 2002), *aff'd.* 334 F.3d 643 (7th Cir. 2003), *cert. denied,* 124 S.Ct. 1069 (2004). Ultimately, the Aimster file-sharing service was not protected under safe harbor provision

of DMCA from contributory copyright infringement claims. The service had used an encryption system, which made it impossible to ascertain which users were transferring which files. This self-imposed limitation did not insulate Aimster from liability. For copyright purposes, "willful blindness is knowledge."[211] Aimster failed to show its service had substantial noninfringing uses. "Aimster has failed to produce any evidence that its service has ever been used for a noninfringing use."[212]

Grokster and Morpheus (after Kazaa defaulted) were initially successful in avoiding vicarious or contributory copyright infringement claims against their file-sharing systems.[213] The court distinguished Napster on the basis that these defendants did not have actual knowledge of the infringement at a time when they could stop it. The court refused to impose copyright liability while acknowledging "the possibility that Defendants may have intentionally structured their business to avoid secondary liability for copyright infringement, while benefiting financially from the illicit draw of their wares."[214] As a consequence of this decision, RIAA has filed suits against individual users responsible for direct copyright infringement though peer-to-peer networks. [The Supreme Court subsequently found the decision in favor of Grokster.]

Software Cases

A number of recent cases have dealt with the application of DMCA to computer software, including software imbedded in consumer products.

Preliminary injunctive relief was granted to the manufacturer of laser printer toner cartridges to enjoin the unauthorized use of computer codes in replacement cartridges under DMCA. *Lexmark Int'l., Inc. v. Static Control Components, Inc.*, 253 F. Supp. 2d 943 (E.D. Ken. 2003). Microchips sold by Static Control circumvented the authentication sequence intended to ensure that only plaintiff's toner cartridges were used with plaintiff's laser printers. The case was vacated by the Sixth Circuit Court of Appeals. 387 F.3d 522 (6th Cir. 2004). The defendant argued the 56-bit lockout program is "trivial in size and function." Lexmark uses the lockout code to enforce a rebate program under which the customer promises to return the empty cartridge to Lexmark for refilling. The authentication sequence controls access to plaintiff's printer engine program and toner-loading

program. The reverse engineering exemption applied to State Control's efforts to circumvent access restrictions to enable interoperability of its independently created non-infringing programs.

The Chamberlain Security Plus garage door opener changes the signal key for the remote control to enhance security. Skylink sells a universal garage door opener to work with the Security Plus system. The court ruled on summary judgment that the defendant's system did not violate DMCA. *Chamberlain Group, Inc. v. Skylink Technologies, Inc.,* 292 F. Supp. 2d 1040 (N.D. Ill. 2003), aff'd, 381 F.3d 1178 (Fed. Cir. 2004). The consumer using the defendant's device authorized access to the code for the garage door opener. Bypassing the original manufacturer's "rolling code" security technology did not violate DMCA. The purchase contract placed no limit on the buyer regarding replacement transmitters. Because the universal remote operated in a variety of garage door openers, it was not primarily designed to circumvent the plaintiff's protective measure.

Safe Harbors for Internet Service Providers

The Statutory Framework

Potential liability for copyright infringement has been seen as an impediment to the growth of electronic commerce. Internet service providers (ISPs)[215] can now be shielded from liability for damages arising from copyright infringement if they register with the U.S. Copyright Office and designate an agent to receive notifications of claimed infringement.[216] DMCA limits the copyright owner to injunctive relief (removal of the infringing material) against an ISP unless the ISP:

- initially placed the material online
- generates, selects, or alters the content of the material
- determines the recipients of the material
- receives a financial benefit directly attributable to a particular act of infringement
- sponsors, endorses, or advertises the material or
- knows, or is aware by notice or other information indicating that the material is infringing.

ISPs are generally protected if they merely operate as a conduit ("transmission ... without modification"),[217] if material provided by a third party is automatically cached,[218] or if the ISP stores or links to infringing material without knowledge of the infringement or a financial benefit attributable to the infringing activity.[219] The ISP must adopt, implement, and notify subscribers of a termination policy for repeat infringers.[220] Knowledge is imputed if the ISP is "aware of facts or circumstances from which infringing activity is apparent."[221]

Transmission Without Modification

An entity providing transmission, routing, or connections is not liable for damages due to the intermediate and transient storage routing or transmission of material if: (1) the transmission was initiated at the direction of a third person; (2) the transmission is carried out through an automatic technical process without selection of material by the service provider; (3) the service provider does not select recipients of the material except as an automatic response to a request; (4) no copy is maintained on the system or network in a manner ordinarily accessible to anyone other than the anticipated recipient or for a longer period than is reasonably necessary for the transmission, routing, or provision of connections; and (5) "the material is transmitted through the system or network without modification of its content."[222]

System Caching

System caching is "intermediate and temporary storage of material" made available online by a third person and transmitted at the direction of another person "through an automatic technical process" making the material available to those who request access from the person who provided the information. A service provider is not liable for system caching if (1) the material is transmitted "without modification to its content;" (2) the service provider complies with rules concerning refreshing, reloading, or updating the material; (3) the service provider does not interfere with the ability of technology associated with the material to return to the person providing the material "information that would have been available" if the material had been obtained directly by a third person; (4) the service provider permits access only to users who have met the conditions established by the person providing the material (such as "payment of a fee or provision of a password"); and (5) the service provider responds expeditiously to a proper notice.[223]

No Benefit and Control

A service provider is not liable for information residing on a system or network at the direction of a user or referring or linking users to a location containing infringing material by using information location tools[224] if (1) the service provider responds expeditiously to remove or disable access and (2) does not have (a) actual or implied knowledge[225] of infringement, (b) a financial benefit attributable to the infringing activity, and (c) the right and ability to control the activity.[226]

Notice and Takedown

Duty to Remove

The ISP must "respond expeditiously to remove, or disable access to, material" made available online by a person other than the service provider "that is claimed to be infringing" in order to qualify for the safe harbor for (1) system caching[227] and (2) lack of benefit and control.[228] Even if the material or activity is ultimately determined not to be infringing, an ISP is not liable for disabling access to or removing material in a good faith response to (1) a notice of infringement[229] or (2) "facts or circumstances from which infringing activity is apparent."[230] Substantial compliance with the notice provision is sufficient.[231] The notice provider is not liable if the notice is merely insufficient and does not "knowingly materially misrepresent ... that material or activity is infringing." [232] The copyright owner is not required to conduct an investigation to establish infringement prior to sending the notice under the DMCA.[233]

Notice Required

The copyright owner must give notice of claimed infringement containing: (1) a physical or electronic signature on behalf of the owner of an exclusive right; (2) identification of the copyrighted work claimed to have been infringed; (3) identification of the material that is claimed to be infringing and information reasonably sufficient to permit the service provider to locate the material;[234] (4) contact information for the complaining party (address, telephone number, and electronic mail address if available); (5) a statement "that the complaining party has a good faith belief that use of the material in the manner complained of is not authorized by the copyright owner, its agent, or the law;" (6) a state-

ment that the information in the notification is accurate and the complaining party is authorized to act on behalf of the owner of an exclusive right.[235] For the system-caching exception, the notice must also include a statement "confirming that the material has been removed from the originating site or access to it has been disabled or that a court has ordered that the material be removed ... or ... access ... disabled."[236]

The notice must be given to the service provider's designated agent.[237] The name, address, phone number, and electronic mail address of the designated agent must be available both through the copyright office and on the service provider's Web site in a location accessible to the public.[238] The registrar of copyrights maintains a current directory of designated agents.[239] The designation must be accompanied by a $20 fee.[240]

A deficient notice does not put the service providers on notice of facts and circumstances from which infringing activity is apparent unless the notice identifies the copyrighted work, the claimed infringing material, and contact information for the complaining party and the service provider fails to promptly attempt to contact the complaining party or take other reasonable steps.[241]

Replacement

The service provider must "take reasonable steps promptly to notify the subscriber that it has removed or disabled access to the material."[242] The source of the material can than have access re-instated by serving a counter notification.

The counter notification must include: (1) a physical or electronic signature of the subscriber; (2) identification of the material removed and the location in which the material appeared before it was removed or access disabled; (3) a statement under penalty of perjury that the subscriber "has a good faith belief that the material was removed or disabled as a result of mistake or misidentification of material to be removed or disabled;" and (4) the subscriber's name, address, and telephone number, and a statement that the subscriber consents to the jurisdiction of the federal district court for the judicial district in which the address is located or, for a subscriber outside the United Sates, for any judicial district in which the service provider may be found and that the subscriber will accept service of process from the complainant.[243]

The service provider must provide a copy of a counter notification to the complainant and inform that person it will replace the material in ten business days (and thereafter actually replace the removed material or cease disabling access in not less than ten, nor more than fourteen days) following receipt of the counter notice unless the complainant has filed an action seeking an injunction.[244]

The service provider's replacement of removed or disabled material in response to a counter notification will not subject it to liability for copyright infringement.[245]

Remedies

Injunction

A service provider is liable for (1) injunctive relief restraining access to the infringing material or prohibiting access to a subscriber or account holder engaging in infringing activity or (2) other relief that "is the least burdensome to the service provider among the forms of relief comparably effective for that purpose."[246] Where the service provider provides only transmission without modification, the court may order the service provider to block access to a specific identified online location outside the United States, but may not otherwise restrain the service provider from providing access to the provider system or network. The court must specifically consider whether the injunction is technically feasible and will significantly burden either the provider or the operation of the provider's system or network.[247]

Additional limitations apply when the service provider is an institution of higher education and a faculty member or graduate student employee is performing a teaching or researching function.[248] The faculty member or graduate student employee is considered a person other than the service provider for purposes of transmission without modification and system caching.[249] Knowledge of the faculty member or graduate student employee is not imputed to the institution for purposes of the benefit and control exemption (liability for information residing on the system or network at the direction of a user or information location tools) if (1) the infringing activities do not involve online "instructional materials that are or were required or recommended within the preceding three-year period, for a course taught at the institution by such faculty member or graduate

student;" (2) the institution has not received more than two notifications of claimed infringement by the faculty member or graduate student in the preceding three-year period; and (3) "the institution provides to all users of its system or network informational materials that accurately describe, and promote compliance with, the laws of the United States relating to copyright."[250]

Damages

Any person misrepresenting that material or activities are infringing or that "material or activity was removed or disabled by mistake or misidentification" is liable for damages, including costs and attorneys fees, incurred by the alleged infringer, by the copyright owner, or the copyright owner's authorized licensee, or by a service provider injured as a result of the service provider's reliance upon the misrepresentation.[251]

Subpoena Rights

A copyright owner can subpoena identifying information for an alleged infringer for use in protecting rights under the Copyright Act. The subpoena authorizes the service provider to provide identifying information available to the service provider.[252]

In *Recording Industry Ass'n of Am. v. Verizon Internet Services, Inc.,* 351 F.3d 1229 (DC Cir. 2003), the court held subpoenas issued under this section cannot be used to obtain user-identifying information if the service provider is merely acting as a conduit for user content in a peer-to-peer network within the safe harbor defined in 512(a) and not subject to the notice and take down provision.[253] The subpoenas must identify the material to be removed or to which access is to be disabled.[254] Verizon can not remove or disable access to material stored on a user's computer. Although "not unsympathetic" to the widespread infringement of recording industry copyrights, the court concluded Congress must amend the statute to extend the subpoena power under 512(h) to the transmission without modification safe harbor.

Litigation

No obligation is imposed on ISPs to seek information indicating materials infringe. Liability for direct infringement against a passive service provider is precluded by the

legislative history of DMCA, but the ISP can be liable for contributory infringement after receiving actual or constructive notice under DMCA.[255] Cases such as *Playboy Enterprises, Inc. v. Webbworld, Inc.*,[256] would still result in liability for Web site operators that sell infringing material and profit from the infringement (even in the form of a fixed monthly fee). Peer-to-peer distribution of copyrighted material does not meet the safe harbors available under DMCA.[257]

eBay has decided to begin monitoring copyrighted material on its site. This is a change from the previous policy based on two California Superior Court cases applying the Communications Decency Act to insulate eBay from liability for unfair competition arising out of sales of counterfeit recordings and sports memorabilia. Qualified immunity under DMCA may be denied if monitoring results on a finding eBay knew and should have known of infringing material. Critics of DMCA argue Napster imposes vicarious liability anyway, so the only recourse is monitoring.

eBay and its employees have been held immune from liability under DMCA safe harbor provisions.[258] The Ninth Circuit recently held that America Online may not be within the safe harbor provision because of a failure to implement the required policy against repeat infringers (notices were forwarded to an inactive e-mail address).[259] An adult Web site age-verification service was not within DMCA safe harbor provisions.[260]

Conclusion

Copyright grants certain exclusive rights to authors (or, in some cases, the author's employer). Universities have often granted faculty ownership of the copyright for "scholarly works," but works such as computer software and databases may not qualify for the scholarly-works exception. Ownership must be addressed in a written (and signed) policy. Recent cases have narrowed the available copyright protection for software, and the scope of protection for databases is subject to continued legislative activity. As copyright law evolves, it will be important to remain aware of these developments and the implications for commercializing works of authorship and related technologies.

Notes

1. The Copyright Act preempts state law protection of rights equivalent to the exclusive rights of the copyright owner. 17 U.S.C. § 301. Generally, a violation of state law that requires an extra element (more than copying) is not preempted. 1 M. Nimmer and D. Nimmer, Copyright 1.01[B][1](a) (1996). Several courts have held that contract restrictions beyond the scope of a copyright owner's exclusive rights are not preempted and are enforceable. See, e.g., *ProCD., Inc. v. Zeidenberg,* 86 F.3d 1447 (7th Cir. 1996) (shrinkwrap restriction on commercial use of CD ROM database); *National Car Rental System, Inc. v. Computer Associates Int'l, Inc.,* 991 F.2d 426, 433 (8th Cir.), cert. denied, 510 U.S. 861 (1993) (restriction on use of software to process third-party data). Thus, contract terms can supplement copyright protection. Use of software outside the scope of the license can constitute both a breach of the license contract and copyright infringement. See, e.g., *S.O.S., Inc. v. Payday, Inc.,* 886 F.2d 1081, 1088 (9th Cir. 1989).
2. U.S. Constitution, Art. 1, § 1, Cl. 8.
3. 17 U.S.C. § 102(a).
4. 17 U.S.C. § 106. Courts are continuing to apply this existing legal structure to the Internet with mixed results. The Working Group on Intellectual Property Rights (a committee appointed by President Clinton in 1993) concluded the right to reproduce is implicated when a work is stored in RAM, scanned, digitized, uploaded, downloaded, or transferred. Intellectual Property and the National Information Infrastructure (1995) (White Paper) at 65-66 (citing *MAI Systems Corp. v. Peak Computer, Inc.,* 991 F.2d 511, 518 (9th Cir. 1993), cert. dismissed, 510 U.S. 1033 (computer program transferred from a permanent storage device to a computer's random access memory). Accord *Sega Enterprises Inc. v. MAPHIA,* 948 F. Supp. 923, 931 (N.D.Cal. 1996). The Working Group recommended "minor clarification and limited amendment" to copyright law to provide the appropriate level of protection on the Internet: Transmission "by any device or process whereby a copy or phonorecord of the work is fixed beyond the place from which it was sent" (downloading and uploading information) is treated as distribution; and importation into the United States by transmission without the authority of the copyright owner would be specifically defined as copyright infringement.

5. 17 U.S.C. § 106A; see Id. § 120 (architectural works).
6. 17 U.S.C. § 102(b). See 37 C.F.R. 202.1 (no protection for ideas, plans, devices, or "words and short phrases"); see also *Southco. Inc. v. Kanebridge Corp.* 390 F.3d 276 (3rd Cir. 2004) (part numbers not protected).
7. 17 U.S.C. § 102(a). See 37 C.F.R. 202.11 (architectural works). Id. § 202.10 (pictorial, graphic, and sculptural works).
8. 17 U.S.C. § 102(b).
9. 17 U.S.C. § 103. See *Munoz v. Albuquerque A.R.T. Co.,* 38 F.3d 1218 (9th Cir. 1994). *Contra Lee v. ART Co.,* 125 F.3d 580 (7th Cir. 1997).
10. *Montgomery v. Noga,* 168 F.3d 1282, 1289 (11th Cir. 1999).
11. *Sega Enterprises Ltd. v. Accolade, Inc.,* 977 F.2d 1510, 1519 (9th Cir. 1992). See *Assessment Technologies of Wis, LLC v. WIREdata Inc.,* 353 F.3d 640 (7th Cir. 2005). See Harris & Rosenfield "Copyright Protection for Genetic Databases," *45 Jurimetrics J* 225 (2005).
12. See, e.g., *Russell v. Price,* 612 F.2d 1123 (9th Cir. 1979).
13. *Cleary v. News Corp.,* 30 F.3d 1255, 1259-60 (9th Cir. 1994). See *Graham v. James,* 144 F.3d 229, 236 (2d. Cir. 1998); 3M Nimmer and D. Nimmer, Copyright, § 8D.63[A][1] at 8D-32 (1998).
14. See, e.g., *Cohen v. Paramount Pictures Corp.,* 845 F.2d 851, 853 (9th Cir. 1988); *CMAX/Cleveland, Inc. v. UCR, Inc.,* 804 F. Supp. 337 (M.D. Ga. 1992). But see *Kennedy v. National Juvenile Detention Assoc.,* 187 F.3d 690 (7th Cir. 1999) cert. denied, 528 U.S. 1159 (2000) (broad grant of authority to reproduce and use a report created an implied license to create derivative works).
15. *Lewis Galoob Toys, Inc. v. Nintendo of America, Inc.,* 964 F.2d 965, 967-68 (9th Cir. 1992), cert. denied, 507 U.S. 985 (1993). The Seventh Circuit does not follow this rule. *Lee v. ART Co.,* 125 F.3d 580 (7th Cir. 1997).
16. *Litchfield v. Spielberg,* 736 F.2d 1352, 1357 (9th Cir. 1989), cert. denied, 470 U.S. 1052 (1985); *M.H. Segan Ltd. Partnership v. Hasbro, Inc.,* 924 F. Supp. 512 (S.D.N.Y. 1996) (a derivative work must borrow substantially from existing works); 1 M. Nimmer and D. Nimmer, Copyrights § 3.01 at 3-3 (1996).
17. 17 U.S.C. §§ 101, 103(a).

18. *Feist Publications, Inc. v. Rural Telephone Service Co.,* 499 U.S. 340, 357, 111 S. Ct. 282, 293-94 (1991). See *Lipton v. Nature Co.,* 71 F.3d 464, 470 (2nd Cir. 1995) (terms used to identify animal groups, arranged based on aesthetic and creative judgment, are protected).
19. *Feist Publications, Inc. v. Rural Telephone Service Co.,* 499 U.S. 340 (1991); *Brown Bag Software v. Symantec Corp.,* 960 F.2d at 1477 n.4; *Apple Computer, Inc. v. Microsoft Corp.,* 779 F. Supp. 133, 135-36 (N.D. Cal. 1991) ("innovative melding of elements from preexisting works"); 17 U.S.C. § 101, 103 ("compilation"); see Nimmer Copyright § 13.03(F)(5) at 13-99 nn.342, 345; R. Harris and S. Rosenfield, "Copyright Protection for Genetic Databases" 45 *Jurimetrics J.* 225 (2005).
20. Compendium II of Copyright Office Practices § 307.1; *Satava v. Lowry* 323 F.3d 805 (9th Cir. 2003).
21. *Feist Publications, Inc. v. Rural Telephone Service Co., Inc.,* 499 U.S. 340, 345, 350-51, (1991). *Feist,* 499 U.S. at 362 (alphabetical white pages listings); *Montgomery County Association of Realtors, Inc. v. Realty Photo Master Corp.,* 878 F. Supp. 804 (D. Md. 1995), aff'd, 91 F.3d 132 (4th Cir. 1996) (protecting computerized real estate listings containing "marketing puffery," "a unique and elaborate system of abbreviations," and an "original presentation and arrangement of the information"). See Sullivan "Where the Creative is the Enemy of the True: Database Protection in the U.S. and Abroad", 29 *AIPLA QJ* 317 (2001). See also *U.S. Copyright Office Circular* 65 (Copyright Registration for Automated Databases).
22. *Feist,* 499 U.S. at 348. *Kregos v. Associated Press,* 937 F.2d 700, 710 (2d Cir. 1991), appeal after remand, 3 F.3d 656 (2d Cir. 1993), cert. denied, 510 U.S. 1112 (1994) (no copyright infringement where defendant's compilation included only six of the ten pitching statistics chosen by plaintiff); *CCC Information Services, Inc. v. Maclean Hunter Market Reports, Inc.,* 44 F.3d 61 (2d Cir. 1994), cert. denied, 516 U.S. 817 (1995)(the republication of the "Red Book" valuations through a computer database service constituted infringement).
23. 197 F.3d 1256 (9th Cir. 1999), See, e.g., *Assessment Technology of WI., Inc. v. Wiredata Inc.,* 350 F3d 640 (7th Cir. 2003); *Mywebgrocer LLC v. Hometown*

Info., Inc., 375 F.3d 190 (2nd Cir. 2004); *Ticketmaster Corp. v. Tickets.com Inc.,* 2003 WL 21406289 (CD Cal March 7, 2003); *Nautical Solutions Marketing, Inc. v. Boats.com,* 2004 WL 78121 (M. D. Fla April 1, 2004); *IMS Inquiry Management Systems Ltd. v. Brookshire Information Systems, Inc.,* 307 F. Supp. 2d 521 (SDNY 2004). But see *Lynx Ventures LLC v. Miller,* 190 F. Supp. 2d 652 (D VT 2002), vacated in unpublished opinion, 45 Fed. Appx. 68 (2d Cir. 2002) (injunction may be appropriate to remedy verbatim copying of database entries).

24. For purposes of proving infringement, the author of a database often includes fictitious entries "created as decoys." *Warren Publishing, Inc. v. Microdos Data Corp.,* 52 F.3d 950, 955 (11th Cir. 1995) (enjoining electronic publication of printed directory of information on cable television systems), vacated, 67 F.3d 276, rehearing en banc, 115 F.3d 1509 (11th Cir. 1997), cert. denied, 522 U.S. 963 (1997). The appearance of such "decoys" in a competitor's database "is strong evidence of copying." Id.
25. For example, a user agreement prohibiting use of "any robot, spider, or automatic device, or manual process to monitor or copy our web pages or the content contained herein" might provide protection under contract law. *eBay, Inc. v. Bidder's Edge, Inc.,* 100 F. Supp. 2d 1058, 1060 (N.D. Cal. 2000) (quotation marks omitted); see also *RealNetworks, Inc. v. Streambox, Inc.,* No. 2:99CV02070, 2000 WL 127311, at *12 (S.D. Wash. Jan. 18, 2000); *Register.com, Inc. v. Verio, Inc.,* 126 F. Supp. 2d 238, 248 (S.D.N.Y. 2000), aff'd, 356 F.3d 393 (2d Cir. 2004).
26. Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the Legal Protection of Databases, 1996 O.J. (L77) 20 (available at http://europa.eu.int/ISPO/ecommerce/legal/documents/396L0009/396L0009_EN.doc); see Case 338/02, *Fixtures Mktg. Ltd. v. Svenska Spel AB* (Nov. 9, 2004), available at http://europa.eu.int/comm/internal_market/copyright/prot-databases/jurisprudence_en.htm; Case 203/02, *British Horseracing Bd. Ltd. v. William Hill Org. Ltd.,* [2005] 1 C.M.L.R. 15 (2004).
27. Id. Article 10(1).
28. Id. 56th recital of the preamble.

29. See *Assessment Technologies of Wis., Inc. v. WIREdata, Inc.,* 350 F.3d 640, 645 (7th Cir. 2003) (noting bills to protect creation of databases have been pending in Congress for years).
30. See *International News Service v. Associated Press,* 248 U.S. 215 (1918); *National Basketball Ass'n v. Motorola Inc.,* 105 F.3d 841 (2d Cir. 1997).
31. See 67 *Pat. Trademark & Copyright Journal* 361 (BNA Feb. 27, 2004) (discussing HR 3261 (Energy and Commerce Committee Print)); Id. at 184 (BNA Dec. 26, 2003) (discussing Senate Bill 692, 108th Congress (2003) and related legislation on digital rights and fair use).
32. 17 U.S.C. 201(c) limits the copyright on a collective work to reproducing and distributing the contribution as part of the collective work. The parties disputed whether an electronic database constitutes the same collective work.
33. 206 F.3d 161 (2nd Cir. 2000).
34. 206 F.3d at 167. See 17 U.S.C. § 103(b) and 201(c). *In Ryan v. Carl Corp.,* 23 F. Supp. 2d 1146 (N.D. Cal. 1998), the court found a document retrieval service (UnCover) that published an Internet database of titles and distributed photocopies of articles violated the author's copyright in the articles. The rights held by the publisher of compilations of articles do not include reproducing individual articles. The publisher paid $7.5 million in settlement with the freelance writers.
35. In re *Literary Works in Electronic Databases Copyright Litigation,* 58 U.S.P.Q.2d 1317, 2001 WL 204212 (S.D. N.Y. 2001).
36. Globe Wire Services, Database Operators Settle Copyright Suit, *The Boston Globe,* March 30, 2005 (available at http://www.boston.com/business/technology/articles/2005/03/30/database_operators_settle_copyright_suit/).
37. *Greenberg v. National Geographic Soc.,* 244 F.3d 1267 (11th Cir. 2001), cert. denied, 534 U.S. 951 (2001). But see *Faulkner v. Mindscape, Inc.,* 2005 WL 503652 (March 4, 2005) (electronic republication was a permissible "revision" and Greenberg not dispositive).
38. Works created prior to January 1, 1978, are governed by the copyright act of 1909. See *Urantia Foundation v. Maaherra,* 895 F. Supp. 1347 (D. Ariz. 1995) (an employment relationship is necessary to establish a work for hire under the 1909 Act) reversed on other grounds, 114 F.3d 955 (9th Cir. 1997); *Playboy*

Enterprises, Inc. v. Dumas, 53 F.3d 549 (2d Cir. 1995), cert. denied, 116 S. Ct. 567 (recognizing judicial expansion of the work for hire doctrine under the 1909 Act to a person engaged to produce a work at the instance and expense of another). Because most material with current market value was created after 1977, this analysis will focus on the current act.

39. 17 U.S.C. § 101.
40. *Playboy Enterprises, Inc. v. Dumas,* 53 F.3d 549, 559 (2d Cir. 1995), cert. denied, 116 S.Ct. 567 (1995); *Schiller & Schmidt, Inc. v. Nordisco Corp.,* 969 F.2d 410 (7th Cir. 1992).
41. *Playboy Enterprises, Inc. v. Dumas,* 53 F.3d at 559; 1 M. Nimmer and D. Nimmer Copyright, § 5.03[B][2][b] at 5-43 (1996).
42. See *Graham v. James,* 144 F.3d 229 (2d Cir. 1998).
43. See e.g., *MacLean Associates, Inc. v. Wm. M. Mercer-Meidinger-Hansen, Inc.,* 952 F.2d 769 (3rd Cir. 1991).
44. *City of Newark v. Beasley,* 883 F. Supp. 3, 7 (D.N.J. 1995); *Avtec Systems, Inc. v. Peiffer,* 21 F.3d 568, 571 (4th Cir. 1994), after remand, 67 F.3d 293 (4th Cir. 1995).
45. See e.g., *Roeslin v. District of Columbia,* 921 F. Supp. 793, 798-99 (D. D.C. 1995); *Avtec Systems, Inc. v. Peiffer,* 21 F.3d 568 (4th Cir. 1994).
46. *Eldred v. Ashcroft,* 537 U.S. 186 (2003).
47. See *Alameda Films SA de CV v. Authors Rights Restoration Corp., Inc.,* 331 F.3d 472 (5th Cir. 2003); *Golan v. Ashcroft, 310 F. Supp.* 2d 1215 (D. Colo. 2004); *Cordon Art BV v. Walker,* 40 U.S.P.Q.2d, 1506 (S.D. Cal. 1996); see 37 C.F.R. § 201.33, Id. § 202.12.
48. 17 U.S.C. § 203.
49. 17 U.S.C. § 203(a)(2). See 37 C.F.R. 201.10 (notices of termination of transfers and licenses).
50. 17 U.S.C. § 203(a).
51. 17 U.S.C. § 203(a)(5).
52. *Marvel Characters, Inc. v. Simon,* 310 F.3d 280, 289-91 (2d Cir. 2002).
53. 17 U.S.C. § 201(b).

54. *Manning v. Parkland College,* 109 F. Supp. 2d 976, 55 U.S.P.Q.2d 1666 (CD Ill. 2000). *Accord Foraste v. Brown University,* 290 F. Supp. 2d 234 (D RI 2003). A patent policy addressed to "all University personnel" has been applied to require assignment of patent rights by a former graduate student. *Univ. of W. Va. v. VanVoorhies,* 278 F.2d 1288 (Fed. Cir. 2002); see *Chou v. Univ. of Chicago,* 254 F.3d 1347, 1357 (Fed. Cir. 2001) (postdoctorate researcher assigned patent for 25 percent of gross royalties and had standing to assert inventorship); *Univ. of Cal. v. Hansen,* 54 U.S.P.Q.2d 1473, 1476 (ED Ca. 1999).
55. Id.
56. Id. See *Hays v. Sony Corp.,* 847 F.2d 412 1091 (7th Cir. 1987) (academic writings were not prepared for the employer). *Cf Shaul v. Cherry Valley-Springfield Central School District,* 363 F.3d 177 (2d Cir. 2004) (High School teacher has no copyright in tests and homework problems).
57. Lape, "Ownership of Copyrightable Works of University Professors: The Interplay Between the Copyright Act and University Copyright Policies," *37 Villanova L. Rev.* 223 (1992) (19 of 70 University policies examined distinguish computer programs from other copyrightable works and claim ownership); Reichman, "Overlapping Proprietary Rights in University-Generated Research Products: The Case of Computer Programs," *47 Colum.-VLA J. L. Arts 51* (1993).
58. *Respect Inc. v. Committee on the Status of Women,* 815 F. Supp., 1112 (N.D. Ill. 1993).
59. 17 U.S.C. § 201(a).
60. 17 U.S.C. § 101. See *Ahn v. Midway Mfg. Co.,* 965 F. Supp. 1134 (N.D. Ill. 1997).
61. P. Goldstein, Copyright: Principles, Law, and Practice, § 4.2.1.2 at 379 (1989). *Accord Erickson v. Trinity Theatre, Inc.,* 13 F.3d 1061, 1070 (7th Cir. 1994); *Childress v. Taylor,* 945 F.2d 500, 506-07 (2d Cir. 1991); *Ashton-Tate Corp. v. Ross,* 916 F.2d 516, 521 (9th Cir. 1990) (naming commands is an insufficient contribution). The alternative de minimis test would only require that the combined product of the joint efforts be copyrightable. 1 M. Nimmer and D. Nimmer Copyright, § 6.07 at 6-23 (1996).
62. See *Weimann v. Freeman,* 868 F.2d 1313 (2d Cir. 1989), cert. denied, 493 U.S. 883 (1989).

63. 35 U.S.C. § 262.
64. *Aalmuhammed v. Lee,* 202 F.3d 1227 (9th Cir. 2000). For a case involving joint authorship of a technical paper by a professor and a graduate student, see *Seshadri v. Kasraian,* 45 U.S.P.Q.2d 1040 (7th Cir. 1997).
65. *Merchant v. Levy,* 92 F.3d 51 (2d Cir. 1996), cert. denied, 117 S. Ct. 943 (1997). Accord *Zuill v. Shanahan,* 80 F.3d 1366, 1369 (9th Cir. 1996), cert denied, 117 S. Ct. 763 (1997); 17 U.S.C. § 507.
66. 17 U.S.C. § 201(d); Id. § 204(a). *Konigsberg Int'l, Inc. v. Rice,* 16 F.3d 355, 356 (9th Cir. 1994); *Effects Associates, Inc. v. Cohen,* 908 F.2d 555, 557 (9th Cir. 1990), cert. denied, 498 U.S. 1103 (1991). A signed written transfer is necessary to establish an exclusive license. *Konigsberg Int'l, Inc. v. Rice,* 16 F.3d 355, 357 (9th Cir. 1994). The writing must be executed more or less contemporaneously with the agreement. Id. But see, *Magnuson v. Video Yesteryear,* 85 F.3d 1424, 1428 (9th Cir. 1996). *Contra Eden Toys, Inc. v. Florelee Undergarment Co., Inc.,* 697 F.2d 27, 36 (2d Cir. 1982). The writing requirement also applies to a transfer between joint owners. *Papa's-June Music, Inc. v. McLean,* 921 F. Supp. 1154, 1158 (S.D.N.Y. 1996).
67. *Playboy Enterprises, Inc. v. Dumas,* 53 F.3d 549, 564 (2nd Cir. 1995), cert. denied, 516 U.S. 1010 (1995); *Schiller & Schmidt, Inc. v. Nordisco Corp.,* 969 F.2d 410 (7th Cir. 1992). See *NetNumina Solutions, Inc. v. DietRehab.com, Inc.,* 2001 WL 455842 (April 6, 2001) (copyright ownership unclear from contract terms).
68. See, e.g., *Essex Music Inc. v. ABKCO Music & Records, Inc.,* 743 F. Supp. 237, 241 (S.D. NY1990); 17 U.S.C. § 501(b).
69. *Gardner v. Nike Inc.,* 279 F.2d 774 (9th Cir. 2002). See *Ward v. National Geographic Society,* 208 F. Supp. 2d 429 (S.D. NY 2002) (1909 Act).
70. See *Cohen v. Paramount Pictures Corp.,* 845 F.2d 851, 853 (9th Cir. 1988).
71. 17 U.S.C. § 201(d).
72. *Accusoft Corp. v. Palo,* 923 F. Supp. 290 (D. Mass. 1996). The parties entered into a settlement agreement that was the subject of continuing litigation five years later. *AccuSoft Corp. v. Palo,* 237 F.3d 31 (1st Cir. 2001).

73. See *Rano v. Sipe Press Inc.,* 987 F.2d 580 (9th Cir. 1993); *Contra Walthal v. Rusk,* 172 F.3d 81 (7th Cir. 1999); *Korman v. HBC Florida Inc.,* 182 F.3d 1291 (11th Cir. 1999).
74. 17 U.S.C. § 101.
75. See *MacLean Associates, Inc. v. Wm. M. Mercer-Meidinger-Hansen, Inc.,* 952 F.2d 769 (3rd Cir. 1991); *Effects Associates, Inc. v. Cohen,* 908 F.2d 555, 556 n. 2 (9th Cir. 1990), cert. denied, 498 U.S. 1103 (1991); 3 M. Nimmer and D. Nimmer, Copyright, § 10.03[A] at 10-41 (1996). See *Foad Consulting Group, Inc. v. Azzalino,* 270 F.3d 821 (9th Cir. 2001) (interpretation of nonexclusive license is a question of state law).
76. *Mendler v. Winterland Production Ltd.,* 207 F.3d 1119 (9th Cir. 2000); *Sun Microsystems, Inc. v. Microsoft, Corp.,* 188 F.3d 1115, 1121 (9th Cir. 1999); *Kepner-Tregoe, Inc. v. Vroom,* 186 F.3d 283 (2nd Cir. 1999); *S.O.S., Inc. v. Payday, Inc.,* 886 F.2d 1081, 1087 (9th Cir. 1989).
77. 154 F.3d at 1113. *Cf, Storm Impact v. Software of the Month Club,* 13 F. Supp. 2d 782 (N.D. Ill. 1998) (court refused to imply license to make commercial use of shareware).
78. *A&M Records, Inc. v. Napster, Inc.,* 239 F.3d 1004, 1026 (9th Cir. 2001). An implied license can only exist where an author creates a copyrighted work with knowledge and intent that the work would be used by another for a specific purpose. *SHL Imaging, Inc. v. Artesian House, Inc.,* 117 F. Supp. 2d 301 (S.D. NY 2000); See *I.A.E., Inc. v. Shaver,* 74 F.3d 768 (7th Cir. 1996). A license will not be implied based only on the "unilateral expectations of one party." Id. See *Attig v. DRG, Inc.,* 2005 WL 730681 (E.D. Pa. March 30, 2005) (implied license to use Web site).
79. See, e.g., *Scheduled Airlines Traffic Offices, Inc., v. Objective, Inc.,* 180 F.3d 583 (4th Cir. 1999) (implied license to complete software where copyright was to be owned by plaintiff with a broad license to defendant); *Krause v. Title Serv. Inc.,* 2005 WL 639420 (2d Cir. March 21, 2005) (buyer of custom software held to have right to modify software for use); *Applied Info. Management v. Icart,* 976 F. Supp. 149, 153 (E.D. NY 1997) (only an owner has rights under 17 U.S.C. § 117(a)).

80. See 17 U.S.C. §§ 203(a)(3); 304(a).
81. 17 U.S.C. § 301. See *Gordon Art BV v. Walker,* 40 U.S.P.Q.2d 1506 (S.D. Cal 1996); *Capitol Records Inc. v. Naxos of Am., Inc.,* 2005 WL 756591 (N.Y. April 5, 2005) (sound recording made prior to February 15, 1972). Use of the copyright notice was required for material published before January 1, 1978. 27 C.F.R. § 202.2.
82. 17 U.S.C. § 412.
83. 17 U.S.C. § 411.
84. See 17 U.S.C. § 408(b); 37 C.F.R. §§ 202.3(b); 202.19.
85. *S.O.S., Inc. v. Payday, Inc.,* 886 F.2d 1081, 1086 (9th Cir. 1989).
86. 17 U.S.C. § 410(c).
87. *Educational Testing Services v. Katzman,* 793 F.2d 533 (3d Cir. 1986); *Szabo v. Errisson,* 68 F.3d 940 (5th Cir. 1995).
88. *Fonar Corp. v. Magnetic Resonance Plus, Inc.,* 920 F. Supp. 508 (S.D.N.Y. 1996), vacated, 105 F.3d 99 (2d Cir. 1997), cert. denied, 118 S. Ct. 265 (1997).
89. 17 U.S.C. § 102(a).
90. 17 U.S.C. § 408(c). See 37 C.F.R. § 202.3(b) (creating 6 classes TX, PA, VA, SR, SE and SE (Group)).
91. Id.
92. 2 Nimmer, Copyright, § 7.20[A] at 7-209; *Royal Source, Inc. v. New Tradition Pipe Co.,* 140 F. Supp. 2d 915 (N.D. Ill. 2001).
93. *Johnson Controls, Inc. v. Phoenix Control Systems, Inc.,* 886 F.2d 1173, 1175 (9th Cir. 1989).
94. *Apple Computer, Inc. v. Microsoft Corp.,* 35 F.3d 1435, 1442 (9th Cir. 1994), cert. denied, 513 U.S. 1184 (1995).
95. See *Johnson Controls,* 886 F.2d at 1176 n. 4.
96. See *American Geophysical Union v. Texaco, Inc.,* 60 F.3d 913 (2d Cir.), cert. denied, 116 S. Ct. 592 (1995) (civil liability for duplication of published scientific articles).
97. *The Boyds Collection Ltd. v. The Bearington Collection, Inc.,* 2005 WL 639420 (M.D. Pa, March 21, 2005).

98. *Religious Tech. Center v. Netcom On-Line Comm. Servs.,* 907 F. Supp. 1361, 1367 (N.D. Cal. 1995); see *Playboy Enterprises, Inc. v. Frena,* 839 F. Supp. 1552, 1559 (M.D. Fla. 1993) ("Intent or knowledge is not an element of infringement, and thus even an innocent infringer is liable...").
99. *Stewart v. Abend,* 495 U.S. 207, 238 (1990).
100. The lack of protection for ideas is closely linked to the merger and scenes a faire defenses. Copyright protection will not extend to "any idea, procedure, process, system, method of operation, concept, principle or discovery regardless of the form in which it is described, explained, illustrated, or embodied. . . ." 17 U.S.C. § 102(b). Under the merger and scenes a faire doctrines, certain elements may not be protected or may be protected only from virtually identical copying. For example, under the merger doctrine, elements of a computer software program dictated by efficiency may be beyond the scope of copyright protection. *Computer Associates International, Inc. v. Altai, Inc.,* 982 F.2d 693, 708 (2d Cir. 1992).
101. *Apple,* 35 F.3d at 1443 (quoting *Herbert Rosenthal Jewelry Corp. v. Kalpakian,* 446 F.2d 738, 742 (9th Cir. 1971)).
102.v *Brown Bag Software v. Symantec Corp.,* 960 F.2d 1465, 1476 (9th Cir. 1992), cert. denied, 513 U.S. 104 (1992).
103. See e.g., *Apple Computer, Inc. v. Microsoft Corp.,* 799 F. Supp. 1006, 1020 (N.D. Cal. 1992), aff'd. 35 F.3d, 435 (9th Cir. 1994).
104. *Feist Publications, Inc. v. Rural Tel. Serv. Co.,* 499 U.S. 340 (1991); See *Brown Bag Software v. Symantec Corp.,* 960 F.2d at 1477 n. 4 (how unprotected elements effect the comparison of the two works "is difficult to say"); *Apple Computer, Inc. v. Microsoft Corp.,* 779 F. Supp. 133, 135-36 (N.D. Cal. 1991) ("innovative melding of elements from pre-existing works"), aff'd., 35 F.3d 1435 (9th Cir. 1994); 17 U.S.C. §§ 101, 103 ("compilation"); see Nimmer, Copyright § 13.03(F)(5) at 13-99 nn. 342, 345.
105. *Apple Computer, Inc. v. Microsoft Corp.,* 821 F. Supp. 616, 623 (N.D. Cal. 1993) (quoting *Harper House, Inc. v. Thomas Nelson, Inc.,* 889 F.2d 197, 205 (9th Cir. 1989)), aff'd, 35 F.3d 1435 (9th Cir. 1994).
106. *Apple,* 35 F.3d at 1447. Accord *Frybarger v. IBM Corp.,* 812 F.2d 525, 530 (9th Cir. 1987) (virtually identical copying required where the expression is "as a practical mater indispensable or at least standard in the treatment" of a given idea).

107. 3 Nimmer, Copyright § 12-04[A](3)[d].
108. See *Fonovisa Inc. v. Cherry Auction,* 76 F.3d 259 (9th Cir. 1996); Annot 14 ALR Fed. 825 (liability as "vicarious" or "contributory" infringer under Federal Copyright Act) (1973)).
109. See *Southern Bell Telephone & Telegraph v. Association of Telephone Directories,* 756 F.2d 801, 811 (11th Cir. 1985); *Shapiro, Bernstein & Co. v. H. L. Green Co.,* 316 F.2d 304, 307 (2d Cir. 1963); *Gershwin Publishing Corp. v. Columbia Artists Management, Inc.,* 443 F.2d 1159 (2d Cir. 1971).
110. 855 F. Supp. at 1329.
111. *Sony Corp. v. Universal Cities Studios,* 464 U.S. 417, 437, 104 S. Ct. 774 (1984); *Gershwin Publishing Corp.,* 443 F.2d 1159, 1162 (2d. Cir., 1971); *A&M Records Inc. v. Abdallah,* 39 U.S.P.Q.2d 1818 (C.D. Cal. 1996); *ISC-Bunker Ramo Corp. v. Altech, Inc.,* 765 F. Supp. 1310, 1332 (N.D. Ill. 1990).
112. *Playboy Enterprises, Inc. v. Frena,* 839 F. Supp. 1552 (M.D. Fla. 1993) (170 photographs uploaded to and downloaded from BBS violated exclusive right to distribute); *Sega Enterprises Ltd. v. MAPHIA,* 857 F. Supp. 679 (N.D. Cal. 1994) (video games); *Central Point Software Inc. v. Nugent,* 903 F. Supp. 1057 (E.D. Tx 1995) (application software).
113. *Bernstein v. JCPenny, Inc.,* 50 U.S.P.Q.2d 1063 (CD Cal. 1998). But see *Intellectual Reserve v. Utah Lighthouse Ministry,* 75 F. Supp. 2d 1290 (D. Utah 1999) (injunction against posting copyrighted material prohibited actively directing users to infringing Web sites.)
114. *Ellison v. Robertson,* 357 F.3d 1072 (9th Cir. 2004) (ISP may be liable for contributory, but not vicarious infringement for storing an unauthorized copy of plaintiff's story). *Religious Technology Center v. NetCom On-line Comm.,* 907 F. Supp. 1361, 1373 (N.D. Cal. 1996) (no direct liability for automatic copying as data was disseminated on the Usenet).
115. 239 F.3d at 1020-22.
116. Id. at 1023-24.
117. 380 F.3d at 1162.
118. Id. (quoting the District Court opinion, 259 F. Supp. 2d 1029, 1037).
119. Id. at 1163 (quoting the District Court opinion, 259 F. Supp. 2d at 1041).

120. Id. at 1165.
121. Id.
122.v See *Perfect 10, Inc. v. Visa International Service Assoc.,* 71 U.S.P.Q.2d 1914 (N.D. Cal. Aug. 5, 2004) (dismissing claims with leave to amend to establish "a relationship between the financial services provided by defendants and the alleged infringing activity" or the right or ability to control the alleged infringing conduct).
123. *Perfect 10, Inc. v. Cybernet Ventures, Inc.,* 213 F. Supp. 2d 1146 (C.D. Cal. 2002) (contributory infringement where the defendant advertised and paid commissions to the Web site and imposed content specific regulations on the Web site).
124. See In Re *Napster, Inc. Copyright Litigation,* 2005 WL 289977 (N.D. Cal. Feb. 3, 2005) (vicarious and contributory copyright infringement claims barred by the statute of limitations). See also *UMG Recordings, Inc. v. Bertelsmann AG,* 222 F.R.D. 408 (N.D. Cal. July 14, 2004) (recognizing it was possible to state a claim "that Berelsmann AG and Hummer Winblad—as entities exercising full control over Napster's operations—were directly responsible for the infringing activity perpetrated by Napster's online users; more than merely knowing of and contributing to the infringing activity, they are alleged to have specifically ordered that such activity take place ... Under well-established Ninth Circuit law, such allegations state a viable claim for relief under theories of both contributory and vicarious liability.") 222 F.R.D. at 412-14.
125. See, e.g., *University City Studios, Inc. v. Corley,* 273 F.3d 429 (2nd Cir. 2001).
126. 17 U.S.C. § 506(a).
127. 18 U.S.C. § 2319(b)(1).
128. 17 U.S.C. § 506(a)(2).
129. In *U.S. v. Manzer,* 69 F.3d 222 (8th Cir. 1995), the defendant was ordered to pay $2.7 million in restitution after a criminal conviction and was also required to pay a civil judgment of $2 million. See generally Harris & Burgess, "Compliance Planning for Intellectual Property Crimes," 2 *Buffalo IP LJ 1* (2003).
130. 17 U.S.C. § 504(c), 505.
131. 17 U.S.C. § 504(b).

132. Some of the cases discussed in this section actually find the plaintiff failed to prove copyrightable material was used. This section is not limited to technical affirmative defenses.
133. *Chavez v. Arte Publico Press,* 157 F.3d 282 (5th Cir. 2000) (en banc) (suit by the plaintiff playwright against the University of Houston for unauthorized publication of her plays was dismissed).
134. 17 U.S.C. § 107. See *Sony Corp. of Am. Inc. v. Universal City Studios, Inc.,* 464 U.S. 417 (1984) (substantial noninfringing uses of technology).
135. See *Campbell v. Acuff-Rose Music, Inc.,* 510 U.S. 569, 114 S.Ct. 1164 (1994); *NVIUM Corp. v. The Ross Institute,* 364 F.3d 471 (2d Cir. 2004) (bad faith considerations are not dispositive in transformative fair use analysis); *Princeton University Press v. Michigan Document Services, Inc.,* 99 F.3d 1381 (6th Cir. 1996), cert. denied, 117 S. Ct. 1336 (1997) (course packs). The computer software cases demonstrate the fact specific native of the fair use analysis. Cf. *Sega Enterprises Ltd. v. Accolade, Inc.,* 977 F.2d 1510 (9th Cir. 1992) (disassembly of object code to understand the functional compatibility requirements constitutes fair use); *Lewis Galoob Toys, Inc. v. Nintendo of America, Inc.,* 964 F.2d 965 (9th Cir. 1992) (use of Game Genie to enhance features of a Nintendo game is fair use of Nintendo's display); with *Atari Games Corp. v. Nintendo of America,* 975 F.2d 832, 843-44 (Fed. Cir. 1992) (not fair use to exploit Nintendo programs). In *Religious Technology Center v. NetCom On-Line Comm. Service, Inc.,* 907 F. Supp. 1361, 1378 n. 25 (N.D. Cal. 1995), the court suggested browsing the Internet creates copies, but constitutes fair use.
136. The District Court also held the "copyright management information" was permissibly omitted because it was not part of the original image. See *Gordon v. Nextel,* 345 F.3d 922 (6th Cir. 2003) (no evidence copyright management information was intentionally removed when illustrations were used in background for a TV commercial).
137. A user agreement prohibiting use of "any robot, spider, or automatic device or manual process to monitor or copy our web pages or the content contained herein" might provide protection under contract law. *EBay, Inc. v. Bidders Edge, Inc.,* 100 F. Supp. 2d 1058 (ND Cal. 2000); *Real Networks, Inc. v. Stream Box,*

Inc., 2000 WL 127311 (W.D. Wash. Jan. 18, 2000); *Register.com v. Verio, Inc.,* 126 F. Supp. 2d 238, 248 (S.D. NY 2000).

138. See *Assessment Technologies of WI, LLC v. WIREdata, Inc.,* 350 F.3d 640 (7th Cir. 2003).
139. Texaco and Publishers Settle Copyright Dispute, *Nat'l L.J.*, Nov. 13, 1995, at B2.
140. The guidelines are published in Copyright Office Circular 21.
141. Published in Copyright Office Circular 21; also available at the Music Library Assn. Web site (www.lib.jmu.edu/org/mla/guidelines).
142. Id.
143. CONFU was convened by the Working Group on Intellectual Property. See note 3 above.
144. Available at www.ccumc.org/copyright/ccguides.html.
145. 17 U.S.C. § 110(b)(2).
146. Id.
147. Id.
148. The act also has application to employees of governmental bodies.
149. These guidelines are published in Copyright Office Circular 21.
150. 17 U.S.C. § 202.
151. 17 U.S.C. § 109(a).
152. *Adobe Systems, Inc. v. Stargate Software, Inc.,* 216 F. Supp. 2d 1051 (N.D. Cal. 2002) (resale contrary to restrictions and end user license). *Adobe Systems Inc. v. One Stop Micro Inc.,* 84 F. Supp. 2d 1086 (ND Cal. 2000) (unrestricted distribution of software intended for educational end users violates license and copyright law); *ISC-Bunker Ramo Corp. v. Altech, Inc.,* 765 F. Supp. 1310, 1331 (N.D. Ill. 1990). *Cf DSC Comm. Corp. v. Pulse Comm., Inc.,* 120 F.3d 1354 (Fed. Cir. 1999) (restrictions on use in license relevant to determining ownership under 17 U.S.C. § 117); but see *Softman Products Co. LLC v. Adobe Systems, Inc.,* 2001 WL 1343955 (CD Cal. October 19, 2001) (economic reality is sale rather than a license).
153. *Microsoft Corp. v. Software Wholesale Club, Inc.,* 129 F. Supp. 2d 995 (SD Tex. 2000); *Microsoft Corp. v. Harmony Computers & Electronics, Inc.,* 846 F. Supp.

208 (E.D.N.Y. 1994). The first-sale doctrine applies to reimported copies manufactured in the U.S. for foreign markets. *Quality King Distributors Inc. v. L'Anza Research Int'l, Inc.,* 523 U.S. 135, 118 S. Ct. 1125 (1998). Importation of copies not made in the U.S. may be prohibited by 17 U.S.C. § 602(a).

154. See *Feist,* 499 U.S. 340 (1991); *E.F. Johnson Co. v. Uniden Corp. of America,* 623 F. Supp. 1485, 1499 (D. Minn. 1985) (originality contributed by author was more than sufficient even though some aspects of the software program are taken from the public domain "and have long been as general scientific use"). See *Southern Building Code Congress Int'l v. Veeck* 293 F.3d791 (2002), cert. denied, 123 S. Ct. 2626 (2003) (building code enacted into law is in the public domain); *Eldred v. Ashcroft,* 537 U.S. 186 (2003) (extending term of copyright and delaying entry of works into the public domain).

155. See *Assessment Technologies of WI, LLC v. WIREdata, Inc.,* 350 F.3d 640 (7th Cir. 2003) (real estate tax assessment data).

156. See *Storm Impact, Inc. v. Software of the Month Club,* 1998 WL 466855 (N.D. Ill. July 29, 1998). *Cf Graham v. James,* 144 F.3d 229 (2d. Cir. 1998) (retrieval software for CD ROM of shareware subject to copyright). See also 37 C.F.R. 201.26 (Recording shareware and public domain software documentation).

157. The GNU General Public License conditions use of the open source software on the surrender of certain copyright protections. See Free Software Found., GNU General Public License (1991), at http:www.fsf.org/licensing/licenses/gpl.html (last modified Feb. 12, 2005). The GNU General Public License terms are published at http://www.gnu.org/licenses/gpl.html (last visited Mar. 2, 2005). Users can copy, modify, and distribute the software in return for a promise to make the derivative work available to the public under the same terms. This approach is sometimes referred to as *copyleft.* Robert W. Gomulkiewicz, "How Copyleft Uses License Rights to Succeed in the Open Source Software Revolution and the Implications for Article 2B," 36 *Hous. L. Rev.* 179, 182 n. 14 (1999); Ira V. Heffan, "Copyright: Licensing Collaborative Works in the Digital Age", 49 *Stan. L. Rev.* 1487, 1491 (1997); Dennis M. Kennedy, "A Primer on Open Source Licensing Legal Issues: Copyright, Copyleft and Copyfuture," 20 *St. Louis U. Pub. L. Rev.* 345, 359-60 (2001). The open source nomenclature refers to the obligation to distribute source

code for all open source software. The open source software can be sold, but the buyer cannot be required to pay any royalty on resale, modification, or redistribution. See generally Open Source Initiative, at http://www.opensource.org (last visited March 2, 2005).

158. *Baker v. Selden,* 101 U.S. 99, 104 (1879).

159. See *Herbert Rosenthal Jewelry Corp. v. Kalpakian,* 446 F.2d 738, 742 (9th Cir. 1971). In the Ninth Circuit merger is analyzed in terms of substantial similarity, not copyrightability. See, e.g., *Apple Computers, Inc. v. Microsoft Corp.,* 759 F. Supp. 1444, 1456 (N.D. Cal. 1991), aff'd, 35 F.3d 1435 (9th Cir. 1994). Thus, courts consider the merger doctrine in determining whether actionable infringement has occurred instead of in determining the scope of copyright protection. See, e.g, *Kregos v. Associated Press,* 937 F.2d 700, 705 (2d Cir. 1991); 3 Nimmer, Copyright § 13.03[B][3] at 13-67.

160. 799 F. Supp. at 1021 (citing Krofft, 562 F.2d at 1167-68). Cf. *Johnson Controls v. Phoenix Control Systems, Inc.,* 886 F.2d 1173, 1175 (9th Cir. 1989) ("where an expression is, as a practical matter, indispensable, or at least standard, in the treatment of a given idea, the expression is protected only against verbatim, or virtually identical copying"). See *Gates Rubber Co. v. Bando Chemical Ind. Inc.,* 9 F.3d 823, 837-838 (10th Cir. 1993); *Harbor Software, Inc. v. Applied Systems, Inc.,* 925 F. Supp. 1042, 1048 (S.D. N.Y. 1996).

161. *Torah Soft Ltd. v. Drosin,* 136 F. Supp. 2d 276 (SD NY 2001).

162. 136 F. Supp. 2d at 290.

163. *Engineering Dynamics v. Structural Software, Inc.,* 46 F.3d 408 (5th Cir. 1995) (input and output formats not protected if they merely reflect industry standards); *Bateman v. Mnemonics, Inc.,* 79 F.3d 1532 (11th Cir. 1996) (copying dictated by compatibility or interoperability requirements is permissible); *Mitel, Inc. v. Iqtel, Inc.,* 896 F. Supp. 1050, 1056 (D. Colo. 1995), aff'd, 124 F.3d 1366 (10th Cir. 1997) (command codes could be copied as "industry standard").

164. *Baystate Technologies v. Bentley Systems,* 946 F. Supp. 1079, 1088-89 (D.Mass. 1996) (data structures dictated by external factors are not protected). *Gates Rubber,* 9 F.3d at 838.

165. 779 F. Supp. at 134. See *Gates Rubber Co. v. Bando Chemical Ind. Ltd.,* 9 F.3d 823, 828 (10th Cir. 1993).

166. 17 U.S.C. § 102(b). See *Southco., Inc. v. Kanebridge Corp.,* 390 F.3d 276 (3rd Cir. 2000) (parts numbering system not protected).
167. Accord *MiTek Holdings, Inc. v. Arce Engineering Co.,* 89 F.3d 1548 (11th Cir. 1996) (menu structure is unprotected "process" and only virtually identical user interface protected).
168. *Lotus v. Borland* holds that a key aspect of the structure and organization of a computer program (the menu command hierarchy) is not eligible for copyright protection. A menu command hierarchy, as a component of the user interface, would not be eligible for protection as a trade secret because it is not—its value is largely derived from its comprehensibility to the user. Nor is trade dress protection available for functional aspects of software. Consequently, under the First Circuit's approach, the menu command hierarchy is protectable (if at all) only under patent law. For a novel command hierarchy, patent protection would be a stronger impediment to innovation that copyright protection. Conversely, if the stringent novelty requirement for patent protection could not be met, no protection would exist for enhanced command hierarchies.
169. 181 F. Supp. 2d at 14.
170. *Alcatel USA Inc. v. DGI Technologies, Inc.,* 166 F.3d 772 (5th Cir. 1999) (license limiting use of operating system software to specific hardware); *Lasercomb America, Inc. v. Reynolds,* 911 F.2d 970 (4th Cir. 1990) (anticompetitive agreement not to write competing software for 99 years in software license agreement). But see *A&M Records, Inc. v. Napster, Inc.,* 239 F.3d 1004, 1026-27 (9th Cir. 2001) (exercise of exclusive right not misuse).
171. 911 F.2d at 978. Accord *Broadcast Music, Inc. v. Hearst/ABC Viacom Entertainment Services,* 746 F. Supp. 320 (S.D. N.Y. 1990); *Contra Bellsouth Advertising & Pub. Corp. v. Donnelley Information Pub., Inc.,* 933 F.2d 952, 961 (11th Cir. 1991), reversed on rehearing, 999 F.2d 1436 (11th Cir., 1993), cert. denied, 510 U.S. 1101 (1994).
172. *DSC Communications Corporation v. DGI Technologies, Inc.,* 81 F.3d 597 (5th Cir. 1996). See *Practice Management Information Corp. v. American Medical Ass'n,* 121 F.3d 516 (9th Cir. 1997), cert. denied, 118 S.Ct. 339 (1997), amended, 133 F.3d 1140.

173. 17 U.S.C. § 1201(a)(1)(A).
174. *RealNetworks, Inc. v. Streambox, Inc.*, 2000 WL 127311 (W.D. Wash. Jan. 18, 2000), (quoting 1 Nimmer Copyright § 12.A17[B].)
175. 17 U.S.C. § 1201(a)(2).
176. 17 U.S.C. § 1201(b)(1).
177. 17 U.S.C. § 1202(c).
178. Id. § 1202(b).
179. Id. § 1202(c).
180. Id.
181. See e.g. www.eff.org. Unintended Consequences: Five Years Under the DMCA v.3 (Sept. 24, 2003).
182. *Universal City Studios v. Reimerdes,* 82 F. Supp. 2d 211, 111 F. Supp. 2d 294 (S.D.N.Y. 2000), aff'd. 273 F.3d 429 (2nd Cir. 2001).
183. *321 Studios v. Metro Goldwyn Mayer Studios, Inc.,* 307 F. Supp. 2d 1085, (ND Cal. 2004); See *Paramount Pictures Corp. v. 321 Studios,* 69 U.S.P.Q.2d 2023 (SDNY Mar. 4, 2004).
184. 17 U.S.C. § 1201(a)(1)(B) & (C).
185. Id. § 1202(a)(1)(C)(iii) & (iv).
186. See 17 U.S.C. § 107. See also Id. § 1201(c) ("Nothing in this section shall affect ... defenses to copyright infringement, including fair use ...").
187. On October 28, 2003, the Librarian of Congress announced the classes of works to be exempted from the DMCA's prohibition against circumvention of technological measures from October 28, 2003, through October 27, 2006. 68 Fed. Reg. 62011 (Oct. 31, 2003) (implementing 17 U.S.C. § 1201(a)(1)(C)). The four classes of works exempted, as provided in revised 37 C.F.R. § 201.40, are (1) certain compilations consisting of lists of Internet locations blocked by commercially marketed filtering software applications, (2) computer programs protected by malfunctioning dongles, (3) computer programs and video games distributed in formats that have become obsolete, (4) literary works distributed in ebook format containing access controls that prevent the enabling of the ebook's read-aloud function.
188. 17 U.S.C. § 1201(d)
189. Id. § 1201(d)(2).

190. Id. § 1201(d)(3).
191. Id. § 1201(d)(4).
192. Id. § 1201(f).
193. Id. § 1201(g).
194. Id. § 1201(j).
195. 17 U.S.C. § 1203(b).
196. 17 U.S.C. § 1203(c)(2) & (3).
197. Id. § 1203(c)(3)(A).
198. Id. § 1203(c)(3)(B).
199. Id. § 1203(c)(4).
200. 17 U.S.C. § 1203(c)(5)(A).
201. Id. § 1203(c)(5)(B).
202. 17 U.S.C. § 1204.
203. 17 U.S.C. § 1204.
204. *Universal City Studios, Inc. v. Reimerdes,* 273 F.3d 429 (2nd Cir. 2001).204 See also *DVD Copy Control Ass'n. Inc. v. Bunner,* 113 Cal. Rptr.2d 338, 60 U.S.P.Q.2d 1803 (Cal Ct. App. 2001), review granted, (Feb. 20, 2002) (prohibiting a publication of trade secret software is an unenforceable prior restraint).
205. An early unreported decision involved the distribution of sound recordings through CompuServe. *Frank Music v. CompuServe Inc.,* 93 Civ. 8153 (S.D.N.Y. filed 11/29/93). Although CompuServe admitted no liability, it paid $568,000 in damages and agreed to make electronic requests to the Harry Fox Agency (the music publisher) before making digital transmissions of sound recordings published by Harry Fox Agency. See Note, "The Digital Performance Right in Sound Recordings Act and its Failure to Address the Issue of Digital Music's New Form of Distribution." 39 *Ariz. L. Rev.* 1361, 1679 (1997).
206. *RIAA v. Diamond Multimedia Systems, Inc.,* 180 F.3d 1072 (9th Cir. 1999). This ruling came full circle when Napster was denied the protection of the Audio Home Recording Act because a computer cannot be a digital audio recording device.
207. See Note "Finding a (DCMA) Safe Harbor in the Turbulent Sea of Online Copyright Liability," 42 *Jurimetrics* 1 (2001).

208. *UMG Recordings, Inc. v. MP3.Com, Inc.*, 92 F. Supp. 2d 349 (SD NY 2000) (database of 45,000 online copies of CDs enjoined), 109 F. Supp. 2d 223 (SD NY 2000) (statutory damages calculated on a per copyrighted CD basis not per song), 56 U.S.P.Q.2d 1374 (SD NY 2000) (damages $25,000 per CD copied).
209. MP3.com reportedly sued its attorneys alleging inadequate copyright advice.
210. See *In re Aimster Copyright Litigation*, 177 F. Supp. 2d 1380 (2001) (consolidating suits against Aimster in N.D. Ill.).
211. 334 F.3d at 650.
212. 334 P.3d at 653. See *Sony Corp. of Am Inc. v. University City Studios, Inc.*, 464 U.S. 417 (1984).
213. *Metro-Goldwyn-Mayer Studios, Inc. v Grokster, Ltd.*, 259 F. Supp. 2d 1029 (C.D. Cal. 2003), aff'd, 380 F.3d 1154 (9th Cir. 2004); reversed, 125 S. Ct. 2764 (20905). See text following note 121.
214. 259 F. Supp. 2d at 1046.
215. A service provider generally includes an entity offering the transmission, routing or connections for digital online communications, including (except for transmission without modification) a "provider of online services or network access, or the operator of the facilities therefore." 17 U.S.C. § 512(k)(1). The broad definition will include many companies providing Internet access.
216. A summary of the regulations is available on the Library of Congress Web site at http://lcweb.loc.gov/copyright/onlinesp/. See Annot. 2001 ALR Fed.2 (Validity, Construction and Application of DMCA).
217. 17 U.S.C. § 512(a).
218. Id. § 512(b).
219. Id. § 512(c) & (d).
220. The service provider must adopt and implement and inform subscribers of a policy that provides for termination of repeat infringers and accommodates "standard technical measures." Standard technical measures means technical measures used by copyright owners to identify or protect copyrighted works that have (1) developed "pursuant to a broad consensus of copyright owners and service providers in an open, fair, voluntary, multi-industry standards process;" (2) are available on reasonable and nondiscriminatory terms; and (3) do not impose "substantial costs

on service providers or substantial burdens on their systems or networks." 17 U.S.C. § 512(i).

221. 17 U.S.C. § 512(c)(1)(A)(ii) or (d)(1)(B).
222. 17 U.S.C. § 512(a).
223. 17 U.S.C. § 512(b).
224. Information location tools include "a directory, index, reference, pointer or hypertext link." 17 U.S.C. § 512(d).
225. Knowledge is imputed if the service provider is "aware of facts or circumstances from which infringing activity is apparent" 17 U.S.C. § 512(c)(1)(A)(ii) or (d)(1)(B).
226. Id. § 512(c) & (d).
227. 17 U.S.C. §512(b)(2)(E).
228. 17 U.S.C. § 512(c)(1)(c) and (d)(3).
229. The registrar of copyrights maintains a current directory of designed agents for receipt of notice. See. www.copyright.gov/onlinesp/list/index.html. The designation must be accompanied by a $20 fee. See 37 C.F.R. 201.38.
230. 17 U.S.C. § 512(g)(1).
231. *ALS Scan Inc. v. RemarQ Communities, Inc.*, 239 F.3d 619 (4th Cir. 2001) (ISP could be liable for failure to take down infringing photographs by two news groups).
232. *Arista Records, Inc v. MP3Board, Inc.*, 2002 WL 1997918 (SDNY Aug. 29, 2002).
233. *Rossi dba InternetMovies.com v. MPAA,* 2003 WL 21511750 (D. Haw. 2003), aff'd, 391 F.3d 1000 (9th Cir. 2004).
234. The reference or link to material or activity claimed to be infringing must be sufficiently identified to permit the service provider to locate that reference or link. 17 U.S.C. § 512(d)(3).
235. 17 U.S.C. § 512(c)(3).
236. Id. § 512(b)(2)(E)(ii).
237. Id. § 512(c)(2).
238. Id.
239. See http://www.copyright.gov/onlinesp/list/index.html.
240. See 37 C.F.R. 201.38.

241. 17 U.S.C. § 512(c)(3)(B).
242. Id. § 512 (g)(2)(A).
243. Id. § 512(g)(3).
244. Id. § 512(g)(2)(B) & (C).
245. Id. § 512(g)(4).
246. 17 U.S.C. § 512(j)(i)(A).
247. Id. § 512(j)(2).
248. Id. § 512(e).
249. Id.
250. Id.
251. Id. § 512(f).
252. Id. § 512(h).
253. Accord *In re Charter Comm., Inc.,* 393 F.3d 771 (8th Cir. 2005).
254. 17 U.S.C. 512(c)(3)(A)(iii), (h)(4).
255. *ALS Scan, Inc. v. RemarQ Communities, Inc.,* 239 F.3d 619 (4th Cir. 2001).
256. 991 F. Supp 543 (N.D. Tx. 1997), aff'd, 168 F3d 486 (5th Cir. 1999).
257. See *A&M Records, Inc. v. Napster, Inc.,* 114 F. Supp. 2d 896 (N.D. Cal. 2000), aff'd in part, 239 F.3d 1004 (9th Cir. 2001), on remand, 2001 WL 227083 (N.D. Cal. March 5, 2001) (Judge Patel ordered Napster to remove songs identified by the plaintiffs within three days); Note "Finding" a (DMCA) Safe Harbor in the Turbulent Sea of Online Copyright Liability," 42 *Jurimetrics* 1 (2001).
258. *Hendrickson v. eBay, Inc.,* 165 F. Supp. 2d 1082 (C.D. Cal. 2001) (the copyright owner did not comply with the requirements of the statutory written notice).
259. *Ellison v. Robertson,* 357 F.3d 1072 (9th Cir. 2004).
260. *Perfect 10, Inc. v. Cybernet Ventures, Inc.,* 213 F. Supp. 2d 1146 (C.D. Cal. 2002); See *Costar Group, Inc. v. Loopnet, Inc.,* 164 F. Supp. 2d 688 (D. Md. 2001) (genuine issues of material fact found to exist regarding protection under the DMCA).

Trademark Primer

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Introduction

This trademark primer is intended both to be of a general education nature for technology transfer practitioners and also an introductory tool for those who might license trademarks in conjunction with technologies. As trademarks are a very distinct form of intellectual property for those in the technology licensing field, having a working knowledge of trademarks is useful.

While trademarks, patents, and copyrights are referred to as *intellectual property,* they are all different. Patents protect inventions, trademarks protect unique product or service identifiers, and copyrights protect original artistic or literary works. While we may know what an invention is, the distinction between a trademark and a copyright is often confused. As an example, the contents (e.g., format, photos, text) of a periodical are protected under copyright law, but the title of the publication (such as *Newsweek*) is protected under trademark law. For copyright information, go to http://www.copyright.gov and for patent information, go to http://www.uspto.gov/main/patents.htm. The U.S. Patent and Trademark Office (USPTO) has a very informative Web site at http://www.uspto.gov/web/menu/tm.html.

Unlike patents and copyrights, a trademark (often called a *brand* or *mark*) is governed under federal *and* state law. A mark is registerable in each state, as well as under the federal trademark law, which is known as the Lanham Act (Title 15 of the United States Code). However, a state registration is only enforceable within that state, while a federal registration provides protection throughout the United States. Registration is not required to establish rights in a mark; actual use in commerce is all that is necessary. As discussed in detail below, a federal application can be filed in the USPTO based only upon a good faith intent that it will be used in interstate commerce, but a registration will not issue

until actual use of the mark occurs in interstate commerce. Unregistered marks are protectable under common law, but only in the market area in which they are actually used.

Terminology

Trademark

A trademark or *brand name* is any word, name, symbol, or device, or any combination which is *adopted and used* in commerce by a manufacturer or business person; *to identify* that person's goods or products; to *distinguish* those goods from goods manufactured or sold by another; and *to indicate* the source of the identified goods.

Examples of what may function as a mark include a:

- Word or group of words, such as a slogan (Tide, Cabbage Patch Kids, Don't Leave Home Without it)
- Logo, symbol, pictorial representation, or design (Nike Swoosh, Golden Arches, five interlocking Olympic rings)
- Combination of a word(s) plus a symbol, pictorial representation, or design (Nestea plus design , Cabbage Patch Kids plus design)
- Numeral(s), letter(s), or combination thereof (501 jeans, IBM computers, V-8 juice)
- Shape of a container or packaging (Coke bottle, conical top of Cross pen, Toberlone chocolate packaging)
- Color (orange for The Home Depot stores, pink for Corning's insulation)
- Sound (lion roar for MGM, chimes for NBC)
- Scent ("The mark consists of a high impact, fresh flower fragrance reminiscent of plumeria blossoms" — U.S. Trademark Registration No. 1,639,128)

Service Mark

A service mark is similar to a trademark, however, it is used in the sale or advertising of services rather than goods. A service mark is used to identify the services of one person and distinguish them from the services of others, such as McDonald's and Office Depot. Service marks are afforded the same legal protection as trademarks and are also registerable in the same manner and with the same effect.

Trade Name

Normally, the name of a business entity is not registerable unless it is used as a trademark or service mark. A trade name is usually identified by its ending in the term *Company/Co., Corporation/Corp., Inc.,* or *Ltd.* (e.g., McDonald's Corp. [trade name] v. McDonald's restaurants [service mark]). Trade-name infringement is actionable under federal and state laws.

Trade Dress

Trademark protection has been expanded by courts beyond words, slogans, symbols, and other devices to protect other distinguishing, albeit unregistered, features of products. While trade dress originally referred exclusively to a product's packaging or *dressing* that was not protectable by registration, the concept has grown to include product designs, the décor of a chain of Mexican restaurants (a festive eating atmosphere having interior dining and patio areas decorated with artifacts, bright colors, paintings, and murals), and even sales techniques, such as simulating adoption procedures and providing birth certificates for the Cabbage Patch Kids dolls.

To recover for trade-dress infringement, a plaintiff must prove by a preponderance of the evidence that (1) its trade dress has obtained "secondary meaning" in the marketplace (*i.e.,* that the primary significance of the trade dress, in the minds of the public, is to identify the product's source rather than the product itself); (2) the trade dress of the two competing products is confusingly similar; and (3) the appropriated features of the trade dress are primarily nonfunctional.

Domain Names

Domain names are addresses on the Internet, like google.com or aol.com, but they do not act as marks in identifying the source of goods or services. However, where domain names are used as something other than merely an address, they may become trademarks. For example, when the term *Google* is used on the home page of google.com or is used in advertising or promoting the Web site, it is being used to identify the source of specific services and, therefore, is acting as a service mark. Similarly, when the *.com* in the domain name is part of the identity of the service, as in advertising for the Amazon.com Web site, the domain name is then functioning as a service mark.

Certification Marks

Certification marks certify that products or services manufactured or provided by others have certain qualities. An example is Vidalia for onions ("The certification mark is intended to be used by persons authorized by the certifier, and will certify that the goods in connection with which it is used are yellow Granex type onions and are grown by authorized growers within the Vidalia onion production area in Georgia as defined in the Georgia Vidalia Onion Act of 1986.").

Collective Marks

Collective marks are used by members of a group or organization to identify the goods they produce or services they provide. An example of a collective mark is ILGU (International Ladies Garment Union).

Selection and Adoption of a Mark

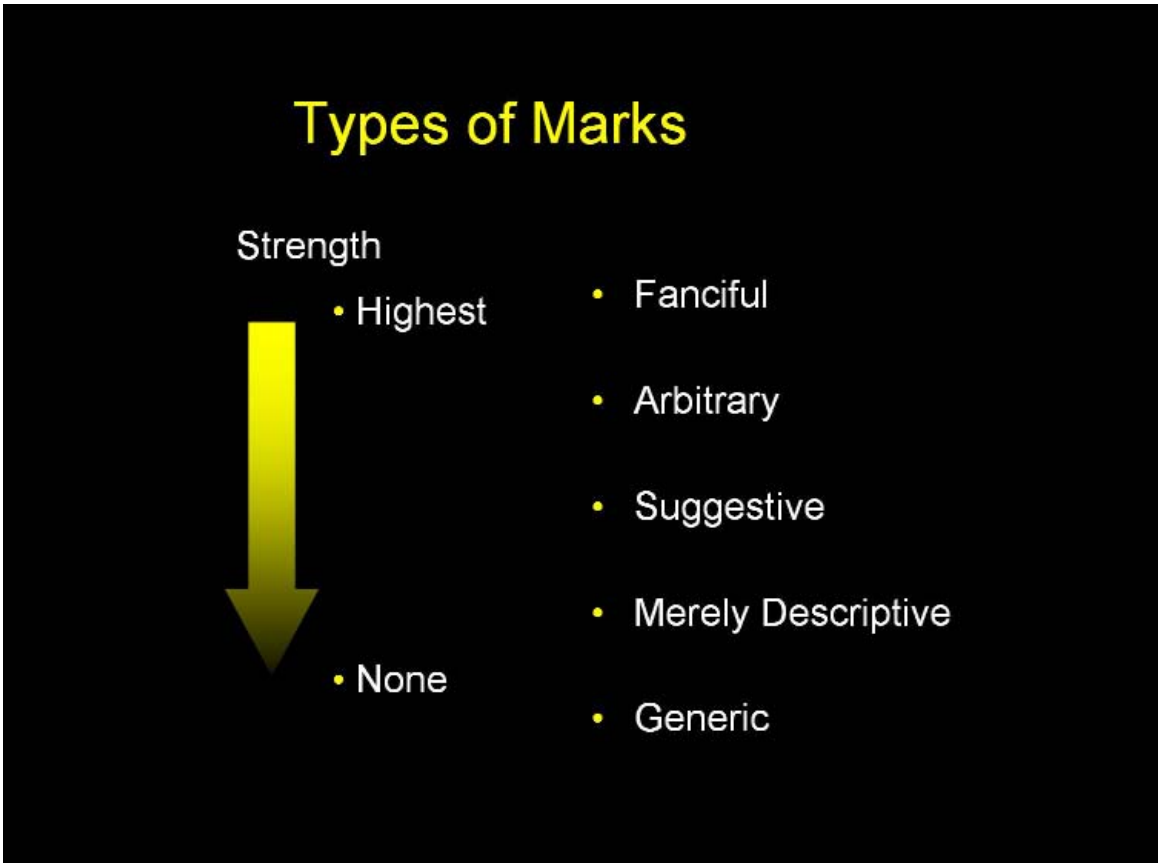
Types of Marks

There is a hierarchy of marks, with the most distinctive marks being afforded a wider scope of protection, the most distinctive being a *fanciful* or *arbitrary* mark, followed by a *suggestive* mark, and, then, a *merely descriptive* mark. (See figure 1.) It is best to select a mark that is fanciful, arbitrary, or suggestive. As one might expect, the more distinctive the mark, the better the chance of protecting and registering it.

Fanciful: a mark that is created solely for the purpose of functioning as a mark and has no other meaning, such as Xerox, Pentium, Kodak, Exxon, Clorox, Kotex, and Polaroid.

Arbitrary: a mark comprising a common word or symbol that is arbitrarily applied to the goods or services in question in such a way that it is not descriptive or suggestive (*i.e.*, the word or words used for the mark do not in any way describe anything about the product at all), such as, Command hair care products, Shell gasoline, Apple computers, Ice Cream chewing gum, Guess? Jeans, and Die-Hard batteries.

Figure 1: Types of Marks



Suggestive: a mark that merely *suggests,* but does not describe qualities or functions of a particular product or service. If the qualities are not instantly apparent and there must be an exercise of imagination to convey the characteristics or qualities of the product or service, the mark is suggestive, such as Crosstalk software, Stronghold nails, 7-Eleven retail store services, Coppertone tanning products, Rapid Shave shaving cream, Gleem toothpaste, Roach Motel roach bait, Woolite wool cleaner, and Honey Maid graham crackers.

Arbitrary, fanciful, and suggestive marks are inherently distinctive and are given a high degree of protection.

Merely descriptive: a merely descriptive mark generally affords the narrowest scope of protection, because it immediately identifies or brings to mind the characteristics, qualities, ingredients, functions, composition, purpose, attribute, use, or other features of a product

or service. It is sometimes difficult to distinguish a suggestive mark from a merely descriptive mark. A merely descriptive term is protectable only upon a showing of a *secondary meaning* or distinctiveness as described above, namely, that the consumer accepts and recognizes the term as denoting only one source (and, thus, functioning as a mark), instead of merely being a descriptor of the goods or services. Courts will often look to the following when deciding whether a term is merely descriptive: (1) the amount and manner of advertising, (2) the volume of sales, (3) the length and manner of the term's use, and (4) the results of consumer surveys.

Marks that have been found to be merely descriptive include: Chap-Stick chapped lip treatment, Shear Pleasure beauty salon, Hair Color so Natural Only Her Hairdresser Knows for Sure hair coloring, Beef and Brew restaurants, Hour after Hour deodorant, and Raisin-Bran cereal.

Thus, the term brilliant would be merely descriptive for diamonds, suggestive for furniture polish, and arbitrary for applesauce.

Generic: Finally, generic terms are the common name of a class of things and are, by definition, incapable of indicating source and can never function as a trademark or service mark (i.e., blended whiskey, computer software, mouse, disk, keyboard).
Generic terms are also those which, at one time, functioned as valid trademarks but which, as a result of widespread use, lost their ability to function as a source identifier and came to mean to the general public the product itself instead of merely one manufacturer's brand or version of the product. Such former trademarks include: aspirin, cellophane, cola, cornflakes, cube steak, dry ice, escalator, high octane, kerosene, lanolin, linoleum, mimeograph, murphy bed, nylon, raisin bran, refrigerator, shredded wheat, thermos, trampoline, yo-yo, monopoly, and zipper. As an example, the term *escalator* was first used as a trademark (Escalator moving stairs) but, over time, the public stopped using the term as a trademark (*i.e.,* as an adjective modifying the noun) and started to designate any moving stairs, regardless of the manufacturer, as an escalator such that the term became the name of the product.

Pre-adoption Investigation

Once the mark is selected, but prior to its use, a thorough search should be undertaken to determine whether the mark is available for both use and federal registration. Sources are listed below.

Records of the U.S. Patent and Trademark Office

A prospective trademark user is charged with constructive notice of any identical or confusingly similar mark that is federally registered. A search of the USPTO records can be conducted online on the USPTO database at http://www.uspto.gov, by hand in the office records, or by means of the Trademarkscan database (File 226) of Dialog services. Also, File 116 (brand names) of Trademarkscan can be searched.

There are several private search firms, including

- Thompson & Thompson (http://www.thomson-thomson.com)
- Dialog (http://www.dialog.com)
- Questel/Orbit (http://www.questel.orbit.com/patents/)
- Micropatent (http://www.micropat.com/trademarkwebindex.html)
- Corsearch (http://www.corsearch.com)

They search the federal register and pending application records as well as phone directories, yellow pages, industrial directories, and state trademark registers in an effort to determine if a particular mark or a similar mark is used by others.

Also, if use of the mark is contemplated in any foreign countries, the trademark and service mark records of those countries should also be searched. Searching of the trademark records of countries such as Canada (File 127), France (File 657), Germany (File 672), and the United Kingdom (File 126) can be performed on the Trademarkscan database of Dialog Services.

State Trademark Records

Again, the Trademarkscan database (for state records, File 246) can be utilized to search the trademark and service mark records of the various states.

Internet Searching

Network Solutions' Web site (http://www.networksolutions.com) provides a convenient search tool to determine if a proposed mark is being used in a domain name and who owns it (the "WOSIT" button). Of course, you can also use your browser to search for directly conflicting Web sites. You can use the Internet to search business names across the country, such as:

- Big Book (http://www.bigbook.com/)
- Switchboard (http://www.switchboard.com/)
- GTE Superpages (http://www.superpages.com)
- World Pages (http://www.worldpages.com/)
- ZIP2(http://www.zip2/com)

Misconceptions

Below is a list of some common misconceptions.

- The fact that one has incorporated, qualified to do business under a name, or registered the name in the assumed name records of a particular state does not automatically give rise to the right to use the name as a mark.
- A person does not have an absolute right to use his or her name as a trademark or service mark.
- Registration in a state of the mark as a trademark or service mark does not necessarily mean it is permissible to use the mark everywhere.
- Even though a mark appears in an abandoned application or an expired registration, the owner of that mark may still be using the mark, and, thus, have protectable common law rights against a subsequent user.

Registration of a Mark in the USPTO

As mentioned above, you do not need to obtain either a state or federal registration to protect a mark as rights in a mark are based upon use, not registration, of the mark. Generally, the first to use a mark or file an intent-to-use application in the USPTO (as described below) for a particular product or service, or for related products and services, is the owner of that mark. However, registration of a mark in the USPTO is highly recom-

mended as the registration will confer significant nationwide benefits on the owner, even if the actual use in commerce of the mark is limited to a small geographical area. That is because the term *commerce* is broadly construed to mean any commerce that may lawfully be regulated by Congress.

The Trademark Act (15 U.S.C. §1127) defines *use in commerce* as follows:

> *The term "use in commerce" means that the bona fide use of a mark in the ordinary course of trade, and not made merely to reserve a right in a mark. For purposes of this Act, a mark shall be deemed to be in use in commerce.*
>
> *(1) on goods when (A) it is placed in any manner on the goods or their containers or the displays associated therewith or on the tags or labels affixed thereto, or if the nature of the goods makes such placement impracticable, then on documents associated with the goods or their sale, and (B) the goods are sold or transported in commerce, and*
>
> *(2) on services when it is used or displayed in the sale or advertising of services and the services are rendered in commerce, or the services are rendered in more than one State or in the United States and a foreign country and the person rendering the services is engaged in commerce in connection with the services.*

Advantages of Registration

Registration of a mark on the Principal Register allows an owner to:

- Prevent registration of the identical or confusingly similar marks
- Secure injunctive relief and damages against infringers nationally in federal court (whereas unregistered marks may be protectable only in the specific market where they are used)
- Assert the registration in federal court as prima facie evidence of the validity of the registration, of the ownership of the mark, and of the right to exclusively use the mark in commerce
- Have the mark treated as incontestable after five years' use

- Eliminate the defense of innocent adoption by anyone using the mark after the date of registration, thereby affording nationwide protection to registered marks, regardless of the areas in which the mark is actually used
- Prevent the importation of goods bearing infringing or counterfeit marks by recording the mark with U.S. Customs

Actual Use vs. Intent-to-Use Applications

A dual-application system exists in the USPTO that permits the filing of trademark/service mark applications based upon an intent to use the mark, as well as applications based on actual use of the mark in commerce. However, while an application may be filed based on a bona fide intent to use the mark, the applicant will still have to make actual use of the mark in commerce before the mark can be registered.

The intent-to-use procedure encourages the early filing of an application because, while the application is pending, the applicant will have the benefit of *constructive use priority.* Thus, subject to the mark actually being registered, the applicant will have prior rights in the mark against all others nationwide (except for those who used the mark before the application was filed, or who filed an earlier application, or who had priority based on a foreign application).

Term of a Federal Registration

Federal trademark/service mark registrations are valid for a period of ten years and are renewable for ten-year periods as long as the mark remains in actual use.

Additionally, between the fifth and sixth year from the date of a federal registration, the registrant must file a declaration or affidavit that the mark is still in use as of that date. An affidavit of use must also be filed in the year prior to the end of each registration term. Failure to file such a statement will cause the registration to be canceled by the USPTO.

State Registrations

A state registration does not confer the same rights and benefits as a federally registered mark. For example, a state registration is enforceable only within that state versus the nationwide protection and constructive notice afforded a mark registered in the USPTO. Thus, usually there is no need to seek a state registration if the mark is registered in the USPTO. A state registration should be obtained only if the mark is not registrable in the USPTO.

Infringement of a Mark

Protection of a mark, whether registered or not, comprises actions against other marks that are likely to cause confusion. For a trademark owner to prevail against an accused party, neither the respective marks nor the respective goods or services need to be identical. Instead, likelihood of confusion (the test for trademark infringement) is determined by considering the following factors, the:

- Strength or weakness of the plaintiff's mark
- Similarity of the marks in sound (e.g., SO found confusingly similar to Esso), appearance (Old Forester infringed by Old Foster), or meaning (Tornado for wire fencing held confusingly similar to Cyclone wire fencing)
- Similarity of the product or services
- Likelihood that the prior owner will bridge the gap between the parties' respective products or services
- Presence or absence of actual confusion (actual confusion obviously being the best test of whether there is a likelihood of confusion occurring between two conflicting marks)
- Defendant's good faith in adopting the mark
- Sophistication of the potential purchasers (buyers of expensive goods may be more discerning purchasers and less likely to be confused between two similar marks for the same goods)
- Channels of trade (are the goods/services sold in the same marketing channels to the same general class of customers?)
- Similarity of the advertising media

The Care and Feeding of Marks

Trademarks and service marks are valuable assets. So, their proper use should be an essential concern of the owner to avoid misuse, which can destroy the legal significance of the mark, resulting in the mark becoming a generic term, as well as create an unfavorable commercial impression.

Guidelines

Proper usage for trademarks and service marks to prevent *genericide* (i.e., a mark becoming generic and, thus, ceasing to indicate source) includes:

- Always use the mark as a proper adjective that modifies a noun, such as Cabbage Patch Kids dolls, Levis jeans, Xerox copy machines
- Never use a mark in the possessive form, in the plural form, or as a verb
- Avoid prefixes, suffixes, additions, or deletions of the mark
- Distinguish the mark in use from surrounding text such as a distinctive typeface, quotation marks, all capital letters or, at the very least, capitalize the first letter of each word of the mark
- For marks registered in the USPTO, use the symbol of registration, namely, ® or the phrase “Registered in the U.S. Patent and Trademark Office” or “Reg. U.S. Pat. Tm. Off.”
- For unregistered marks, use either the informal notice “TM” or “SM” or an asterisk indicating “A trademark/service mark of XYZ Company.”

The following ditty was a prize-winning submission at the Coca-Cola Co., which should be kept in mind as a reminder with respect to the proper usage of any mark:

Three laws bind the Kingdom of Coke
This trio must never be broke
The “C” should be tall
Not possessive at all
And the plural should never be spoke

Licenses

Never allow a third-party to use your mark without entering into a written license agreement, which, at a minimum, provides for your ability to monitor and control the nature and

quality of the goods or services in connection with which the mark is used by the licensee. Otherwise, you may have a *naked license,* which could dilute the distinctiveness of your mark. Also, provide in any license agreement for the licensee to notify you of potentially infringing marks so that you may police your mark, as unauthorized uses of your mark will dilute your scope of protection.

Assignments

An assignment of a mark must be in writing and, whether registered or not, must include "the good will of the business associated with the mark" or the assignment is invalid. The basis for that is that a mark is merely the symbol of good will (i.e., the owner's reputation for quality in connection with the goods or services sold under the mark). An assignment of a mark without the accompanying good will is an *assignment in gross* and is invalid. Also, an intent-to-use application cannot be assigned as there is nothing to assign until the mark is in actual use.

Anti-Bioterrorism Laws that Affect Technology Transfer at Academic Institutions

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In the post-September 11, 2001, era, the threat of biological terrorism is receiving heightened focus by law enforcement and national security agencies, and there is an increase in the scope and type of laws and regulations governing transfer of biological materials and related equipment. Two new federal laws, the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act)[1] and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BPARA)[2] and its regulations impose new and very stringent requirements on the transfer of, and on certain other activities with, biological agents, toxins, and related equipment.

All Biological Agents and Toxins and Their Delivery Systems: USA PATRIOT Act

One provision of the USA PATRIOT Act, Section 817(1), amends Chapter 10 of Title 18 of the United States Code (U.S. Criminal Code) to criminalize a greater range of activities involving all types of biological agents and toxins (not only the so-called select agents addressed later in this chapter under "Select Biological Agents and Toxins: USA PATRIOT Act") and the equipment that may be considered a delivery system for such materials.[3] Section 175(a) of the U.S. Criminal Code remains in effect and provides that anyone who "*knowingly* develops, produces, stockpiles, *transfers, acquires,* retains, or possesses *any* biological agent, toxin, or delivery system *for use as a weapon,*" not including (under Section 175(b)) activities that are prophylactic, protective, or peaceful, or who knowingly helps a foreign state or organization to do so, or who attempts to do these things, may be punished by criminal fines of up to $500,000 for entities, and by imprisonment for any term of years or for life, criminal fines of up to $250,000, or by both for individuals, both subject to increase or decrease for certain aggravating and mitigating factors.[4]

Section 817(1) of the USA PATRIOT Act amends Section 175(b) of the U.S. Criminal Code, renumbering this section as 175(c) and redefining "[f]or use as a weapon" as this phrase is used throughout Section 175 to include "development, production, *transfer, acquisition,* retention, or possession of any biological agent, toxin, or delivery system for other than prophylactic, protective, bona fide *research,* or other peaceful purposes."[5] Section 817(1) then creates a new Section 175(b), adding as an additional offense *"knowingly possess[ing]* any biological agent, toxin, or delivery system *of a type or in a quantity* that, under the circumstances, is *not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose."*[6] This offense excludes any biological agent or toxin that is in its natural environment, meaning that the agent or toxin "has not been cultivated, collected, or otherwise extracted from its natural source."[7] This additional offense makes the mere knowing possession of agents or toxins a crime under certain circumstances, even if it is not known that the agents or toxins or their delivery systems are "for use as a weapon."[8] Such offense is punishable by up to ten years in prison, or criminal fines of up to $250,000, or both for individuals, and by criminal fines of up to $500,000 for entities, both subject to increase or decrease for certain aggravating or mitigating factors.[9]

Section 175 (a) and new Sections 175(b) and 175 (c) of the U.S. Criminal Code expand the criminal prohibition beyond knowing involvement with biological materials for use as a weapon. These sections together make it a crime for the university or college, as well as for the individual researcher or other personnel (such as research support staff, purchasing staff, shipping and receiving staff, or, potentially, technology transfer office staff, depending on their roles), to possess *or transfer or acquire* any biological agent or toxin or related equipment of a type or in a quantity that is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose.[10] And outsiders such as federal law enforcement and, ultimately, the courts, not the researchers or other personnel of universities, will decide what is "reasonably justified," making it critical for institutions and individuals to view the law from a law enforcement perspective. The section criminalizes a wide range of activities and omissions involving biological agents and toxins and their delivery systems and requires a significant reorientation for academic researchers and technology transfer office staff who have not been accustomed to strict controls on

how long excess materials are retained or on how much of a material is acquired or transferred in the first place. Regarding research and technology transfer from a law enforcement perspective is not a natural act in our academic culture.

Technology transfer offices may be implicated by these statutory provisions in connection with material transfer agreements or other technology transfers involving any type of biological materials or equipment or tools related to such materials. Whether "transferring" or "acquiring" biological materials or related equipment under Sections 175 (a) through (c) of the U.S. Criminal Code includes contracting for rights to transfer or acquire such materials is an open issue. There is very good argument that acquiring or conferring rights to transfer or acquire a material is distinct from the actual transfer or acquisition. However, it is prudent for technology transfer offices to support the institution's, faculty's, and other personnel's compliance and to avoid participating in or perpetuating a proscribed activity. Because an agreement to convey rights to transfer or acquire biological materials will likely ultimately result in their transfer or acquisition, the quantity and type of biological materials being transferred or acquired and the purpose for the transfer or acquisition should be carefully considered to limit the quantity to that which is really necessary for current or imminent academic research or other prophylactic peaceful purposes. It is helpful for the operative agreements to state the prophylactic peaceful purpose for the transfer or acquisition and to include a statement that quantities and types of materials covered are only what are needed for that purpose. Where a university is transferring materials to a commercial company and there is a real question as to whether they will be used only for prophylactic peaceful purposes, a representation and warranty by the company may be warranted.

Select Biological Agents and Toxins: USA PATRIOT Act

Another section of the USA PATRIOT Act, Section 817(2), adds § 175b to the U.S. Criminal Code, prohibiting any "restricted person" from shipping, *transporting, possessing, or receiving* biological agents or toxins listed and not exempted under the regulations implementing Section 511(d)(1) of the Antiterrorism and Effective Death Penalty Act of 1996 (AEDPA)[11] and making such activities by a restricted person a federal crime.[12] This prohibition applies to the individual, not to the institution, and, in addition to covering

individuals who are researchers using listed, nonexempt agents or toxins, may cover individuals who are responsible for arranging for or undertaking shipping, receiving, transportation, or storage of listed, nonexempt agents or toxins.[13] Violations by individuals of new Section 175b are subject to criminal penalties of up to ten years in prison and/or up to $250,000 in fines, subject to increase or decrease for certain aggravating or mitigating factors.[14] Although the prohibition applies directly to the individual, the institution could suffer adverse publicity and unwanted law enforcement attention if its researcher or other personnel were to violate the prohibition. The enactment of BPARA, which is companion legislation to the USA PATRIOT Act, extends an obligation to the institution to not allow access to select agents and toxins to "restricted persons," as addressed in "Select Biological Agents and Toxins: BPARA" later in this chapter.

Individuals who are restricted persons under the USA PATRIOT Act are not permitted to continue to possess the relevant biological agents and toxins or to ship, receive, or transport them, or, with the enactment of BPARA, to have access to them.[15] Any support, custodial, and shipping and receiving staff, or, depending on staff's role, any technology transfer staff, who is a restricted person and who may need to undertake or arrange for any of the prohibited activities, must at least be reassigned to work that does not involve proscribed activities with listed, nonexempt agents or toxins and may lose his or her position if this is not possible; and any researcher who is a restricted person must abandon research involving such agents or toxins and change the focus of his or her career, very significant effects indeed.

A restricted person under the USA PATRIOT Act is anyone who:

- *is* under indictment for, or *has been* convicted of, a crime punishable by imprisonment for over one year [(e.g., felonies, including certain moving motor vehicle violations), whether or not the person was actually punished with imprisonment]; or
- *is* a fugitive from justice; or
- *is* an unlawful user of any controlled substance [e.g., an illegal drug or a drug used illegally as defined and listed in 21 U.S.C. 802 and 812]; or
- *is* an alien illegally or unlawfully in the United States; or

- *has been* adjudicated as a mental defective or *has been* committed to any mental institution [which could arguably include anyone who has been self-committed for depression or drug or alcohol abuse, although this has not been decided by a court]; or
- *is* an alien (including a legal alien in the United States, but not including a lawful permanent resident of the United States or green-card holder, who is a national of [Cuba, Iran, North Korea, Iraq, Libya, Sudan, or Syria], which includes individuals with dual citizenship of the United States and of any of the listed countries);
- *has been* [dishonorably] discharged from the Armed Services of the United States.[16]

The technology transfer office should clearly have no role in arranging for shipping, transporting, or receiving materials in order to support the distinction between arranging for these regulated activities and merely contracting for rights to transfer or acquire materials. If this distinction is made and followed, technology transfer staff should not be engaged in activities covered by Section 817(2) of the USA PATRIOT Act.

Select Biological Agents and Toxins: BPARA

Another federal law, BPARA,[17] was enacted by Congress and signed into law by the president on June 12, 2002, to further protect against the use of certain particularly dangerous biological agents and toxins in bioterrorism. Title II, Subtitle A, Section 201(a) of BPARA (Title II) adds a new Section 351A to the Public Health Service Act,[18] which is a companion federal law to Section 817 of the USA PATRIOT Act. The USA PATRIOT Act continues to apply to individuals who are restricted persons with respect to so-called select biological agents and toxins. Title II, Subtitle A, is implemented by the secretary of Health and Human Services (HHS) and its Centers for Disease Control and Prevention (CDC). Title II, Subtitle B, creates the Agricultural Bioterrorism Protection Act of 2002 and is implemented by the secretary of agriculture (USDA) and USDA's Animal and Plant Health Inspection Service (APHIS). Violations of BPARA are punishable by criminal fines of up to $500,000 for entities and criminal fines of up to $250,000, imprisonment for up to five years, or both, for individuals, and civil penalties of up to $250,000 for individuals and $500,000 for entities.[19]

Title II is broader in its application than Section 817(2) of the USA PATRIOT Act or Section 511(e)-(g) of AEDPA, applying to any institution, as well as to any individual, who possesses, uses, or *transfers* certain select biological agents and toxins that have the potential to pose a severe risk to human, animal, or plant health, or animal or plant products.[20] Such institutions and individuals may allow "access" to select agents and toxins only to individuals who have been approved for access by the applicable secretary and cleared through background checks by the attorney general or who are escorted by those who are cleared in accordance with implementing regulations.[21] *Access* is a broad term that may apply not only to researchers and others who work directly with listed agents and toxins, but also to custodial and shipping and receiving staff who enter areas where listed agents or toxins are stored, used, shipped, or received and who either have possession, or have the ability to gain possession, of a listed nonexempt agent or toxin.[22] Export control laws and regulations continue to govern the transfer to foreign nationals or U.S. citizens abroad of biological agents and toxins and certain related equipment that are governed by BPARA (as well as additional chemicals, agents, and toxins), the provision of controlled technical information about such materials or items to foreign nationals or U.S. citizens abroad, and the provision of controlled technical information about such materials or items to foreign nationals in the United States.[23] U.S. Department of Transportation laws and regulations continue to apply to transportation of agents and toxins as hazardous materials.[24]

Generally, Title II of BPARA and its implementing regulations prohibit any entity or individual from possessing, using, transferring, receiving, or having access to listed, nonexempt biological agents and toxins within the United States, except for a "lawful purpose"[25] and, unless and until the entity, any individual who owns or controls the entity, certain individuals who are responsible for BPARA compliance at the entity (i.e., the institution's designated BPARA responsible officials), and all individuals who will possess, use, transfer, or have unescorted access to the agents or toxins are registered with the secretary of HHS or agriculture,[26] as appropriate, following their clearance through background checks, referred to as *security risk assessments,* to be conducted by the attorney general.[27] Approval of registration is conditioned on the development and implementation of security, safety, training, emergency preparedness and response,

record-keeping, transfer protocols, and other measures in accordance with the regulations implementing the act.[28] BPARA required the secretaries of HHS and agriculture (secretaries) to adopt regulations by mid-December 2002 to implement the act.[29]

The regulatory requirements under BPARA are extensive and complex. This chapter will not fully address them and provides references to further resource materials for those who are interested in all of the details. It is particularly important, however, for technology transfer offices to understand the requirements related to transfers so that they do not unintentionally contribute to a violation. The term *transfer* is used in BPARA and its regulations, although this law and its regulations are aimed at physical security, not information or rights transfers. Arranging for rights to transfer materials under a material transfer agreement is arguably distinct from an actual transfer, and even from arranging for an actual transfer. By limiting the role of the technology transfer office staff to arranging for conveyance of rights, not to any aspect of the actual transfer of, or transfer arrangements for, biological materials, and by making clear that the institution's BPARA responsible officials for the select agent and toxin program are the only persons who have the authority to actually transfer covered materials, it should be possible to exclude the technology transfer process from activities regulated under BPARA.

The terms of material transfer and other technology transfer agreements can support the institution's compliance with BPARA. An entity or other person is prohibited from transferring any listed, nonexempt agent or toxin to another entity or other person in the United States, or from receiving any such agents or toxins from any entity or person outside the United States, unless (1) the sender and recipient are registered appropriately; (2) the sender and the U.S. recipient fulfill the CDC's or APHIS' requirements, as applicable, for securing agency pretransfer approval and for filing transfer documentation with the agency, and are registered under the regulations for the agent or toxin being transferred, (3) the sender from outside the United States satisfies all import requirements, (4) all senders satisfy applicable packaging and shipping laws, (5) the BPARA responsible official for the recipient sends the required transfer documentation to the sender and the HHS or USDA secretary (through CDC or APHIS) within two business days of receipt of such agent or toxin, (6) the BPARA responsible official for the recipient "immediately" reports

to the secretary (through CDC or APHIS) if the agent or toxin is not received within forty-eight hours of its expected delivery or if their packaging is leaking or damaged, and (7) the BPARA responsible official for the transferor also ensures that listed, nonexempt agents and toxins are only transferred to recipients who are registered and in compliance with the transfer requirements of BPARA regulations.[30] These requirements do not apply to intra-entity transfers if the sender and the recipient are under the same registration certificate, but do apply if the sender and the recipient are not under the same registration certificate.[31] If an entity has more than one location, it will have a separate registration certificate for each location and, consequently, will have to comply with transfer requirements when transferring agents or toxins from one of its locations to any other.[32] The technology or material transfer agreement should reflect an awareness of these requirements (without listing them) and an agreement to adhere to them.

It is prudent for material transfer agreements and other technology transfer agreements that may apply to regulated biological materials to incorporate a statement that the sender and the receiver of the subject materials will comply with all applicable U.S. laws and regulations relating to the transfer, acquisition, receipt, possession, shipping, and/or transport of the materials, including without limitation BPARA and USA PATRIOT Act, to the extent applicable. Where biological materials are being transferred or received, the technology transfer office should confer with the institution's BPARA responsible official prior to entering the relevant agreement to determine whether the materials are regulated by BPARA or by Section 817(2) of the USA PATRIOT Act, and to determine whether the prerequisites to the transfer have been met. If covered biologicals are involved, the institution's BPARA responsible official will need to arrange for the transfer, and the transferring and receiving institutions will need to satisfy the regulatory requirement before the transfer is initiated.

For more information about the USA PATRIOT Act bioterrorism provisions and BPARA and its regulations, see parts II and III of my article "The War on Terrorism Affects the Academy: Principal Post-September 11, 2001 Federal Anti-Terrorism Statutes, Regulations and Policies that Apply to Colleges and Universities," published in Vol. 30, No. 2, of the *Journal of College and University Law.* The author's copy is available at http://web.mit.edu/srcounsel/resource/Final25_Apr04_JLKversion_Same_As_PDF_Journal_version.pdf.[33]

Notes

1. USA PATRIOT Act, Pub. L. No. 107-56, 115 Stat. 272 (2001)(to be codified in scattered sections of 5, 8, 12, 15, 18, 20, 21, 22, 28, 31, 42, 47, 49, 50 U.S.C.).
2. BPARA, Pub. L. No. 107-188, 116 Stat. 594 (2002). See "Select Biological Agents and Toxins: BPARA" in this chapter.
3. USA PATRIOT Act § 817(1), 115 Stat. at 385-86 (codified at 18 U.S.C.A. § 175 (2000 & West Supp. 2003)).
4. 18 U.S.C.A. § 175(a), (b) (2000 & West Supp. 2003); § 3571(b)-(d) (2000) (emphasis added).
5. USA PATRIOT Act § 817(1), 115 Stat. at 385 (codified at 18 U.S.C.A. § 175(c) (2000 & West Supp. 2003)) (emphasis added).
6. Id. § 817(1), 115 Stat. at 385 (codified at 18 U.S.C.A. § 175(b)) (emphasis added).
7. Id.
8. Id.
9. 18 U.S.C.A. §§ 175(b), 3571(b)-(d).
10. See supra notes 3-9. Unlike the prohibition in Section 817(2) of the USA PATRIOT Act, which created 18 U.S.C. § 175b to prohibit certain individuals from possessing, receiving, or transporting biological agents and toxins listed and not exempted under the regulations implementing Section 511(d)(1) of the Antiterrorism and Effective Death Penalty Act of 1996 and its successor, Section 817(1) of the USA PATRIOT Act amends the U.S. Criminal Code to prohibit certain activities involving *any* biological agent or toxin, or related equipment, that are not "reasonably justified" for prophylactic, bona fide research, or other peaceful purposes, without regard to whether the agent or toxin is listed in or exempted from regulations and without any specific quantity thresholds. *Id.; c.f. infra* notes 11-16 and accompanying text.
11. Pub. L. No. 104-132, 110 Stat. 1214 (1996) (codified as amended in scattered sections 7, 8, 15, 18, 19, 21, 22, 28, 40, 42 U.S.C.) [hereinafter AEDPA]. The AEDPA's regulations at 42 C.F.R. § 72.6(h), (j) listed select biological agents and toxins that are subject to registration requirements of the secretary of Health and Human Services, Centers for Disease Control and Prevention, and exempted certain agents and toxins, including toxins with a Lethal Dose 50 "for vertebrates of more than 100 nanograms per kilogram of body weight [ ] used for legitimate medical purposes or

biomedical research" or not being adequately potent to pose a severe risk to human health. 42 C.F.R. § 72.6(h) (2003).

12. USA PATRIOT Act § 817(2), 115 Stat. at 385-86 (codified at 18 U.S.C.A. § 175b (West Supp. 2003)).
13. See id., 115 Stat. at 386.
14. See 18 U.S.C.A. § 175b(c) (West Supp. 2003), § 3571(b), (d) (2000).
15. USA PATRIOT Act § 817(2), 115 Stat. at 385-86 (codified at 18 U.S.C.A. § 175b(a)). See infra "Select Biological Agents and Toxins: BPARA" in this chapter.
16. USA PATRIOT Act § 817(2), 115 Stat. at 386 (codified at 18 U.S.C.A. § 175b(d)(2)) (emphasis added). There are no reported cases interpreting the USA PATRIOT Act's definition of a restricted person or challenging the constitutionality of the act's criteria for defining a restricted person. One may question whether the USA PATRIOT Act's definition of restricted person would be upheld in the event of a constitutional challenge. With the possible exception of the sixth criterion (i.e., aliens from the enumerated countries), however, the definition of restricted person does not appear to include any classification that receives heightened judicial scrutiny. Consequently, it is likely in most constitutional challenges that the government would have to show only that it has a rational basis for determining the categories of restricted persons in relation to achieving the act's legitimate national security purposes, and that such determinations, as implemented by the executive branch, are not arbitrary or capricious. See *City of Cleburne v. Cleburne Living Center,* 473 U.S. 432, 440 (1985) (noting that legislation is presumed to be valid and will be sustained if the classification drawn by the statute is rationally related to a legitimate state interest); 5 U.S.C.A. § 706(2)(A) (1996 & West Supp. 2003) (arbitrary and capricious standard for administrative agency action). Moreover, where national security is involved, Congress is given considerable discretion. See *Hirabayashi v. United States,* 320 U.S. 81, 93 (1943). This standard requiring a reasonable relationship of the law's requirements to legitimate government purposes is generally easy to meet. The standard may be somewhat more difficult to meet, however, in narrow circumstances such as where an individual is determined to be a restricted person only because he or she was discharged dishonorably from the military due only to sexual orientation. In that particular case, there may be good arguments that the law should be held to violate the First Amendment or the Fourteenth Amendment

(substantive due process or equal protection), made applicable to the federal government through the Fifth Amendment; however, the law otherwise is likely to be upheld.

In contrast to review of the classification of individuals as restricted persons under most of the USA PATRIOT Act criteria to which the reasonable relationship standard applies, the classification of individuals as restricted persons based only on their national origin is likely subject to a stricter standard of judicial review, the strict scrutiny standard. As the Supreme Court held in *City of Cleburne,* "race, alienage, or national origin . . . are so seldom relevant to the achievement of any legitimate state interest that laws grounded in such considerations are deemed to reflect prejudice and antipathy. . . . [T]hese laws are subjected to strict scrutiny and will be sustained only if they are suitably tailored to serve a compelling state interest." *City of Cleburne,* 473 U.S. at 440. Despite this heightened standard of judicial review, it may be difficult to prevail in a constitutional challenge of even this criterion. The enumeration of a limited list of countries in the definition of a restricted person is tied to those countries that are suspected to be state sponsors of terrorism, and arguably may be closely related to the USA PATRIOT Act's goal of preventing or deterring bioterrorist acts. In the current environment, the objective tailoring of criterion may be narrow enough to survive a challenge. The question under strict scrutiny is whether all legal aliens of such countries must be excluded from research with select biological agents and toxins in order to achieve the compelling interest of preventing bioterrorism.

It is important for academic institutions to document how the government is administering and enforcing the law to ensure that the relevant agencies are not doing so in a discriminatory fashion (e.g., against individuals of only certain religions) or in a manner that otherwise abuses the agencies' discretion. It is also important for academic institutions to document the adverse effect of the law on important research if the academic community seeks to influence the development of more effective laws against bioterrorism that will safeguard our nation without undermining the research that makes the United States an international leader of education, innovation, and the world economy. While such information may be of limited value in a constitutional challenge to the USA PATRIOT Act's restricted persons criteria, it would support reasoned arguments to Congress for amendments to the law.

17. Supra note 2. The BPARA's implementing regulations are at 42 C.F.R. pt. 73, 7 C.F.R. pt. 331, and 9 C.F.R. pt. 121.
18. BPARA § 201(a), 116 Stat. at 637-46 (codified at 42 U.S.C.A. § 262a).
19. Id. § 201(a), 116 Stat. at 637 (codified at 42 U.S.C.A. § 262a(i)) (adding Section 351A(i) to the Public Health Service Act) (establishing civil monetary penalties); § 212(i), 116 Stat. at 655-56 (codified at 7 U.S.C.A. § 8401(i) (West Supp. 2003)) (establishing civil monetary penalties); § 231, 116 Stat. at 660 (codified at 18 U.S.C.A. § 175b (West Supp. 2003)) (establishing criminal penalties); 18 U.S.C.A. § 3571 (2000) (criminal fines and sentences). See also *Centers for Disease Control and Prevention, Select Agent Program: FAQ for New Regulation,* available at http://www.cdc.gov/od/sap/faq.htm.
20. See BPARA § 201(a), 116 Stat. at 637-46 (codified at 42 U.S.C.A. § 262a); § 212, 116 Stat. at 647-56 (codified at 7 U.S.C.A. § 8401 (West Supp. 2003)). The AEDPA and its regulations required the registration of listed nonexempt agents only prior to their transfer or receipt. AEDPA § 511(d)-(e), 110 Stat. 1214, 1284-85 (not codified, but published as 42 U.S.C.A. § 262 note (2003)). The USA PATRIOT Act only prohibits "restricted persons" from shipping, transporting, possessing, and receiving listed, nonexempt agents and toxins. USA PATRIOT Act § 817(2), 115 Stat. at 385-86 (codified at 18 U.S.C.A. § 175b (West Supp. 2003)). APHIS' list of regulated agents and toxins under Section 212 of the BPARA and its regulations is new, although APHIS had previously regulated and continues to regulate the importation and interstate transportation of certain organisms, diseased or treated animals, and plant pests. See 9 C.F.R. pt. 122 (2004); 7 C.F.R. § 330.200 (2004).
21. BPARA § 201(a), 116 Stat. at 638-42 (codified at 42 U.S.C.A. § 262a) (adding Section 351A(b)-(e) to the Public Health Service Act); § 212(b)-(e), 116 Stat. at 647-52 (codified at 7 U.S.C.A. § 8401 (West Supp. 2003)); 42 C.F.R. 73.7, 73.10; 9 C.F.R. §§ 121.7, 121.10; 7 C.F.R. §§ 331.7, 331.10.
22. See 42 C.F.R. § 73.10(b); 9 C.F.R. § 121.10(b); 7 C.F.R. § 331.10(b).
23. Jamie Lewis Keith, "United States Export Controls and Embargoes May Apply to Technology Transfer" in *AUTM Technology Transfer Practice Manual,* 3rd ed. (Northbrook, IL: Association of University Managers, 2006), Vol. 1, Pt. 1, Ch. 11.
24. See 49 C.F.R. pts. 171-180 (2003).
25. See BPARA § 201(a), 116 Stat. at 637-46 (codified at 42 U.S.C.A. § 262a); § 212, 116 Stat. at 647-56 (codified at 7 U.S.C.A. § 8401).

26. See BPARA § 201(a), 116 Stat. at 638-39 (codified at 42 U.S.C.A. § 262a) (adding Section 351A(d) to the Public Health Service Act); § 212(d), 116 Stat. at 648-49 (codified at 7 U.S.C.A. § 8401); 42 C.F.R. §§ 73.7; 9 C.F.R. § 121.7; 7 C.F.R. § 331.7 (registration requirements).
27. See BPARA § 201(a), 116 Stat. at 639-42 (codified at 42 U.S.C.A. § 262a) (adding Section 351A(e) to the Public Health Service Act); § 212(e), 116 Stat. at 649-52 (codified at 7 U.S.C.A. § 8401); 42 C.F.R. § 73.7, 73.10; 9 C.F.R. §§ 121.7, 121.10; 7 C.F.R. §§ 331.7, 331.10.
28. Id.
29. BPARA § 202(b), 116 Stat. at 646 (not codified, but published as 42 U.S.C.A. § 262a note (2003)); § 213(c), 116 Stat. at 657 (not codified, but published as 7 U.S.C.A. § 8401 note (West Supp. 2003)). Within 180 days after enactment of the BPARA, the HHS secretary was required to promulgate an interim final rule for carrying out the provisions of § 351A of the Public Health Service Act (i.e., Title II of the BPARA), provided that the effective dates for such regulations must "minimize disruption of research or educational projects that involve [listed] biological agents and toxins . . . and that were underway as of the effective date of such rule." *Id.* § 202(b)-(c), 116 Stat. at 646-47 (not codified, but published as 42 U.S.C.A. § 262a note). On March 18, 2005, final regulations were published. 70 Fed. Reg. 13242, 13294 (March 18, 2005).
30. 42 C.F.R. §73.16; 9 C.F.R. § 121.16; 7 C.F.R. § 331.16.
31 See 42 C.F.R. §§ 73.16(a), n.4; 73.7(g); 9 C.F.R. §§ 121.16(a), n.13, 121.7(g); 7 C.F.R. §§331.16(a), n.8, 331.7(g). Note that export control laws and regulations govern transfers abroad of certain agents, toxins and other chemicals. See Jamie Lewis Keith, "United States Export Controls and Embargoes May Apply to Technology Transfer" in *AUTM Technology Transfer Practice Manual,* 3rd ed. (Northbrook, IL: Association of University Managers, 2006), Vol. 1, Pt. 1, Ch. 11.
32. Id. (The regulations provide that the transfer requirements do not apply to intra-entity transfers if the same registration certificate applies; consequently, if there are two locations and two certificates, the transfer requirements do apply). A campus may be one location.
33. Portions of other publications by the author are included in or adapted for this chapter.

United States Export Controls and Embargoes May Apply to Technology Transfers

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In the post-September 11, 2001, world, the U.S. federal government regards export controls and embargoes as tools to guard against terrorism and is devoting heightened focus to compliance and enforcement in academic research settings. Congress and the defense-oriented interests at the export control, major science funding, and defense agencies are presently questioning and assessing the effectiveness of export controls to stem what they perceive to be a threat that academic institutions might transfer sensitive technology to potential terrorists. Although most institutions do not invest oversight or primary administration of export controls compliance in the technology transfer office, it is critical that university researchers, as well as the technology transfer offices that help them license and patent technologies they develop, understand the applicable export control and embargo rules, exclusions, and licensing exemptions to avoid running afoul of the requirements. The technology transfer office should coordinate with the office that administers the institution's export-compliance program and its expert in export controls, as well as with the inventors, to ensure that the technology transfer process does not contribute to a violation of export controls or embargoes. A violation may be brought about through a material or technology transfer agreement or through a technical assistance agreement that calls for transfers or disclosures of technical information or materials or items that require a license or approval when none exists or is being sought. To avoid such facilitation of a violation, the technology transfer office should be well-versed in the prerequisites for exclusions from export controls and exemptions from export and deemed export-licensing requirements and in the triggers of possible licensing that should precipitate consultation with export experts at the institution.

Export controls apply to many types of equipment, chemicals, biological agents and toxins, materials, goods, and software code (materials or items) that are used by academic

research institutions and to certain information, training, and instruction relating to controlled materials or items.[1] (This does not mean, however, that a license is required for most activities on campus as discussed below.) It is worthy of note that since September 11, 2001, Congress and federal agencies have particularly sought to increase regulations of chemicals, biological materials, and related equipment for law enforcement and antiterrorism purposes, rather than only for the traditional personal safety purposes. Covered chemicals and biologicals are subject to the requirements of export controls in addition to the requirements of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BPARA)[2] and its regulations and the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act).[3] This heightened law-enforcement (not just research safety) focus on chemicals and biologicals has a potentially great effect on academic research and technology transfers, as the life sciences are among the fastest growing areas of academic research.[4]

Academic institutions and their researchers can take steps to qualify much of their campus research and teaching for regulatory exclusions from export controls, but they must understand and adhere to the prerequisites for exclusion. There are a number of exclusions from export controls and exemptions from licensing that permit the transfer of qualifying information, but not related materials or items, without a license. Particular care is needed for transfers of materials or items. Institutions and individuals must obtain export licenses, fulfill their conditions, and otherwise comply with export controls when an exclusion or exemption does not apply and a license is required.[5]

The export regulations are complicated, and determining whether or not materials or items or related technical information are controlled is an intricate and time-consuming task, requiring both technical expertise about the characteristics of the materials or items and technology and regulatory expertise about the controls.[6] If only technical information, not materials or items, is involved in a proposed transfer or disclosure to anyone abroad or to a foreign national in the U.S., it is easier to first consider whether the fundamental research, publicly available/public domain, or another exclusion from controls (discussed later under “Regulatory Exclusions”) applies. If an exclusion applies, it is not necessary

to undertake the detailed and complicated assessment of whether export controls apply to the information and, if so, whether a license is required and is likely to be obtainable.

Where materials or items are proposed to be transferred abroad, or an exclusion from controls or exemption from licensing does not apply to a proposed transfer or disclosure of technical information abroad or to a foreign national in the U.S., it is necessary to determine whether export controls apply. If so, it is imperative to confirm that an export or deemed export license has been obtained and that the proposed transfer or disclosure complies with the license conditions before the transfer occurs. It is also highly advisable to have this confirmation before entering into a material or technology transfer agreement that contractually compels a transfer or disclosure that may require a license or may be prohibited.

Violation of export controls and embargoes can carry significant criminal and civil penalties against the individual involved as well as against the institution.[7] The possibility of losing export privileges and of damage to an institution's reputation are also significant penalties for violations.

Regulatory Regimes

The three principal export control and embargo regimes in the United States are the International Traffic in Arms Regulations (ITAR) of the State Department, the Export Administration Regulations (EAR) of the Commerce Department, and the regulations of the Office of Foreign Assets Control (OFAC) of the Treasury Department.[8] Export controls and embargoes are intended to advance the United States' foreign policy goals; to restrict exports of goods, technology, and information that could enhance the military potential or economic superiority of other countries (both adversaries and friendly nations); to prevent the proliferation of nuclear, chemical, and biological weapons of mass destruction; to prevent terrorism; and to perform the United States' obligations under various foreign treaties and agreements with other nations, such as the Nuclear Non-Proliferation Treaty.[9] When export controls apply, they apply to U.S.-origin materials or items and certain related information, training, and instruction, wherever they are located or take place, whether in the United States or abroad.[10] Underlying the export control regimes

and their criminal and civil penalties for violations, is the principle that it is a privilege and not a right for U.S. citizens and permanent residents (individuals and entities) to export covered materials or items and certain related technical information.[11]

Export Administration Act

EAR,[12] implementing the Export Administration Act of 1979, as amended,[13] among other federal authorizations,[14] is administered by the Bureau of Industry and Security (BIS) of the Commerce Department under the secretary for industry and security. EAR generally governs exports[15] of materials or items that may have a dual use, meaning that they are largely commercial but may have both commercial and military applications, as well as certain technologies and technical data (i.e., information and data beyond general and basic marketing materials on use, development, or production of materials or items controlled for such information).[16] EAR lists the items subject to its regulation on the Commerce Control List (CCL), which includes a catchall category, EAR 99.[17]

International Traffic in Arms Regulations

ITAR,[18] implementing the Arms Export Control Act among other federal authorizations,[19] is administered by the directorate of defense trade controls (DDTC) of the State Department, under the under secretary for international security and the assistant secretary for political-military affairs.[20] ITAR generally governs exports[21] of defense articles (i.e., certain materials or items), related technical data (i.e., information beyond basic marketing material on use, development, and production of controlled materials or items) and defense services (i.e., information, training, and instruction) *(a)* that are "specifically designed, developed, configured, adapted, or modified for a military application . . . [do] not have a predominant civil application[], and . . . [do] not have [a] performance equivalent . . . to those of an article or service used for civil applications" or *(b)* that are "specifically designed, developed, configured, adapted, or modified for a military application, and [have] a significant military or intelligence applicability."[22] Many regulated defense articles are listed on the United States Munitions List (USML),[23] although this list is not as specific as the CCL under EAR, and ITAR regulation relies as well on general standards. ITAR regulates materials or items (and related information constituting defense services or technical data) that are designed to kill or injure in a military context, as well as

materials or items and certain related information that are designed to defend against such death and injury.[24] Seemingly innocuous equipment, such as mini research submersibles (even if not intended by the creator for a military application),[25] can be included on the USML depending on their configuration. Articles or services that, in the State Department's judgment, are specifically designed, developed, configured, adapted, or modified for a military application and do not have predominant civil applications, as well as those articles and services with significant military or intelligence application that, in the State Department's judgment, require control, fall under the ITAR.[26] In addition to regulating USML-listed defense articles and related defense services and technical data, ITAR regulates other materials or items (and certain related information, training and instruction), when there is reason to know that they will be used in or for weapons of mass destruction or when they are designed or modified for military use.[27]

Office of Foreign Assets Control Regulations

Supplementing EAR and ITAR are the regulations of OFAC within the U.S. Treasury Department. OFAC regulations govern payments to, transfers of any service, materials, or items of value to, or travel to, certain sanctioned and embargoed foreign countries, and transactions with and transfers to certain embargoed individual and entity end users that are deemed to be involved in terrorism, the drug trade, or other illicit activities.[28] These regulations implement United States' trade embargoes and economic sanctions against specified countries, entities, and individuals.[29] OFAC's regulations prohibit the payment or transfer of any thing and any service of value to embargoed countries, subject to the scope of the particular embargoes applicable to each country, and to specified embargoed individuals and organizations whether or not their countries are embargoed.[30] OFAC regulations may apply to bar transfer of information (even in academic research collaborations and technology transfers), providing instruction or services, planning and conducting surveys and conferences, physically transferring materials or items, entering contracts, making payments, and traveling, even when exclusions from EAR and/or ITAR apply. Similarly, the fact that an OFAC general license or other permission allows a transfer under OFAC of items or materials or technical information does not mean that the transfer is permitted under EAR or ITAR without an export license. Evaluation of the requirements of each regulatory scheme is required.

Basic Prohibitions and Requirements

As a general matter, an *export* under EAR and ITAR is the transfer outside of the United States or to a foreign embassy of any controlled materials or items (i.e., those on the CCL or USML or otherwise covered by the regulations). An export also includes the disclosure abroad of any controlled software, or of controlled technologies or technical data (i.e., information and data beyond general and basic marketing materials) on use, development, or production of materials or items controlled for use (i.e., "operation, installation...maintenance...repair, overhaul, and [/or] refurbishing"), product development or production technology or technical data,[31] regardless of the medium in which such information is transmitted (whether oral, visual, via computer or other electronic means, wire, radio transmission, or physical conveyance).[32] Export also includes transfer of ownership or control of such, materials or items.[33] It does not matter for purposes of defining export whether the recipient abroad is a U.S. citizen or lawful permanent resident or is a foreign national. The mere travel abroad by an individual whose personal knowledge includes controlled technical data/technologies, however, is not an export as long as the controlled information is not communicated to anyone abroad. Material transfer agreements and other technology transfer agreements involving transferees in foreign countries may present export issues.[34]

Deemed exports are the transfer or disclosure, visually, electronically, or in any other medium, of controlled software or technologies or technical data (i.e., information, beyond general and basic marketing materials, on use, development, or production of materials or items controlled for such technology and data) to a foreign entity or individual in the U.S. Deemed exports do not include the mere transfer in the U.S. of the actual controlled materials or items without any accompanying information. Campuses, and U.S. university technology transfers, are rife with opportunities for deemed exports because many U.S. universities' students, faculties, visitors, research collaborators, and licensees are foreign.[35]

Unless an exclusion from regulation applies, before any export or deemed export of materials or items (or of related information constituting technical data or technologies) regulated under ITAR may occur, and before some such exports or deemed exports

regulated under EAR may occur, a license must be obtained from the relevant agency, DDTC, or BIS.[36] This means that, before a faculty member may send (and before a technology transfer office should contract to send) controlled materials or items or controlled technologies or technical data to a United States or foreign colleague in a foreign country—and before they may collaborate with, share technical information with, or train a United States or foreign colleague abroad or a foreign colleague in the United States in any manner that involves transfer of controlled technical data or technologies—a license must be obtained, if an exclusion or exemption from regulation does not apply and a license is required. (Exclusions and exemptions generally, with very limited exceptions, cover information but not materials or items as addressed below.) Obtaining a license can take a few months (typical) to half a year or, in some cases, longer. Licenses may be required for exports and deemed exports to friendly foreign locales and nationals, such as those in Canada, countries in Europe, and Australia, as well as for exports and deemed exports to unfriendly or terrorist foreign locales and nationals.[37] If an exclusion from regulation does not apply and a license is required but denied, the export abroad or deemed export in the United States (even on campus) may not occur and the faculty member or technology transfer office may not pursue the activities that require an export license.[38]

Transferring export-controlled information (controlled technology or technical data) to a foreign jurisdiction as part of a technology disclosure in order to seek patent protection in that jurisdiction does not require an EAR or ITAR license.[39] However, transfer of the same information abroad to anyone for any other purpose, or in the U.S. to a foreign national, before the patent is published may require a license (depending on the applicable controls and nationalities involved and on whether exclusions from controls may apply).

When an EAR or ITAR license is not required for controlled materials or items, and when an export is exempt from licensing, export documentation is still required.[40] Even if an exclusion from export controls applies, as discussed below, there may still be restrictions on travel to, payments to, and/or transactions and transfers with certain embargoed locales, organizations, and/or individuals under OFAC regulations.[41]

Before any contract is entered into for the transfer of materials or items or related information, or for the provision of any payment, advice, or service, OFAC sanctions lists should be consulted to ensure that the transfer is not to a prohibited person, entity, or country.[42] If it is prohibited, the transfer may not be made unless OFAC grants a license. The likelihood of obtaining a license depends on which sanctioned country, individual, or entity is involved, why the sanction was imposed, and the sanction's terms and conditions.

Regulatory Exclusions

The following part summarizes two exclusions from export controls, the *fundamental research* exclusion and the *publicly available/public domain* exclusion, that are most relevant to and useful in a technology transfer context. As discussed below, restrictions and other conditions limiting access to and dissemination of research results under material transfer and license agreements may arguably destroy the fundamental research and public availability/public domain exclusions from export controls if they are, in effect, proprietary information publication or dissemination restrictions. Research licenses that allow unrestricted sublicenses for research use may arguably preserve the exclusions, although expert counsel should be consulted when there is a question. Special care is warranted to determine whether export controls apply to materials or items and related technology/technical data that are subject to exclusive licensing agreements before entering into such agreements.

If it is the individual's or institution's intention to patent export-controlled intellectual property that also is sought to be covered by an exclusion from EAR and ITAR, careful consideration must be given on how to accomplish both objectives and which exclusion to apply. In order to qualify intellectual property for patent protection, it is necessary to adhere to certain patenting prerequisites prior to making the intellectual property publicly available under EAR or putting it into the public domain under ITAR through a means other than publication of the patent application in the patent process. To refrain from a too-early publication that may affect patentability, while also qualifying for an export exclusion allowing participation of foreign nationals in the related research, it may be necessary to apply, and to satisfy the prerequisites for, the fundamental research exclusion (and not to apply the publicly available/public domain exclusions), during development of

the intellectual property (before the patent is published). This means, among other pre-requisites, ensuring that any foreign nationals participate in the research and receive otherwise controlled information only on campus in the United States.

Fundamental Research Information

The *U.S. university fundamental research* exclusion under EAR and ITAR is one of the most commonly known and applied exclusions from export controls by academic research institutions. This exclusion is based on National Security Decision Directive 189 (NSDD 189), which defines *fundamental research* as "basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community, as distinguished from proprietary research and from industrial development, design, production and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons."[43] NSDD 189 was issued during the Reagan administration despite concerns that the former Soviet Union might take advantage of U.S. openness. The directive provides that the classification process is the appropriate means of securing information related to fundamental research by colleges and universities when security is warranted and otherwise, except as required by statute, fundamental U.S. university research should be freely disseminated because the dissemination of knowledge supports the nation's security. The George W. Bush administration, in November 2001 and again in October 2004, confirmed that NSDD 189 continues to be the policy of the federal government.[44]

The fundamental research exclusion under EAR and ITAR applies literally to *(a)* information (but not to export-controlled materials or items) *(b)* resulting from or arising during "basic and applied research in science and engineering" *(c)* conducted at an "accredited institution of higher education" (EAR) or "higher learning" (ITAR) *(d)* "located in the United States" *(e)* that is "ordinarily published and shared broadly within the scientific community" and *(f)* that is not "restricted for proprietary reasons or specific national security reasons" (EAR) or subject to "specific U.S. Government access and dissemination controls" (ITAR).[45] This exclusion permits U.S. universities to allow foreign members of their communities (e.g., students, faculty, and visitors) to participate in research projects involving export-controlled information on campus in the United States. Also, once

fundamental research is created on campus in the U.S. in accordance with the exclusion's prerequisites, the research results (otherwise controlled information constituting technologies and technical data) may be transferred abroad without restriction. The nature and purpose of this information is to be public; hence it is excluded, not merely exempted, from controls. This exclusion does not allow the transfer of controlled materials or items abroad (with very limited exceptions under ITAR).[46] There is a dialogue under way among academic research institutions and the federal government (particularly the Commerce Department) concerning whether or not this exclusion allows the deemed export, while conducting fundamental research on campus in the United States, of certain controlled technologies and technical data that do not arise during or result from, but that are used in or necessary for, fundamental research. It has long been the reasonable interpretation of the academic research community that, for fundamental research to have any meaning, it must allow research group members to freely disclose among themselves information on how to use controlled equipment in the research. The government has not previously challenged this interpretation, but is now examining its wisdom.

If a university accepts a condition from a government agency funding the research that requires the agency's approval prior to publication of the research results or restricts access to the research results or participation in the research to U.S. citizens, the fundamental research exclusion is destroyed and export controls apply if the materials or items and/or related information constituting technologies or technical data are controlled under EAR or ITAR.[47] Seeking to impose such restrictions rather than classifying research that presents real security concerns is contrary to the principles of NSDD 189.[48] The same loss of exclusion occurs if a nongovernment sponsor imposes proprietary restrictions on publication of or access to the research results.

Note, however, that a short delay in publication only for purposes of allowing sponsor review to ensure that sponsor-provided proprietary information is not inadvertently included or to allow the institution or the sponsor to seek patent protection is permitted without destroying the exclusion.[49] In any event, the results of the research itself may not be proprietary or the fundamental research exclusion will not apply.[50] And, if a sponsor provides proprietary information to the university researcher concerning materials or

items or related technologies or technical data that are subject to EAR or ITAR, that sponsor information is subject to export controls, and both the university and the sponsor must comply.[51]

Public Information

The public domain exclusion under ITAR[52] and the publicly available exclusion under EAR[53] are the broadest available exclusions from export controls. These exclusions, if they apply, allow deemed exports of otherwise controlled information to foreign nationals in the United States and exports of otherwise controlled information to anyone abroad, without export controls applying at all, even if the export involves a prohibited, embargoed, or restricted country.

These exclusions expressly apply only to the export or deemed export of information (including technologies and technical data), not to the export of USML- or CCL-listed or otherwise controlled materials or items (such as covered equipment, encrypted software, chemicals, or biological agents or toxins), or services. To qualify for these exclusions, there must not be a reason to believe that the exported information will be used in or for weapons of mass destruction. In addition, the federal government must not have imposed export controls or restrictions as a funding condition. It is critical that neither the institution, nor the principal investigator, agrees to restrict public disclosure, to limit participation by foreign nationals, or to accept any other export controls as a condition to funding, or the information will not qualify for these public domain and public availability exclusions.[54]

Information, including nonencrypted software code, that is already published (not just ordinarily published), through or at one or more of the following means or outlets are in the public domain or are publicly available and, consequently, are not subject to export controls: *(a)* libraries open to the public, including most university libraries; *(b)* unrestricted subscriptions, newsstands, and/or bookstores for a price not exceeding reproduction and distribution costs plus a reasonable profit; *(c)* U.S. patents and open (published) patent applications; *(d)* conferences, meetings, seminars, trade shows, and exhibitions held in the United States, which are generally open to the public for a fee reasonably related to the cost and at which attendees may take notes and from which attendees may

leave with their notes; and *(e)* Web sites that are accessible to the public, free of charge, and without the host's knowledge or control of who visits or downloads software or information.[55] If only EAR information and nonencrypted software are involved (and ITAR is definitely not implicated), the information and software may be published through or at such conferences, meetings, seminars, trade shows, and exhibitions, wherever they are held (in the United States or abroad).[56] Only these methods of publication prescribed in the regulations qualify, regardless of how readily available the information is around the world. However, the public domain/publicly available exclusions are very useful and are much broader in their coverage than is the fundamental U.S. university research exclusion, which (with a very limited exception) can only be exercised on campus in the U.S.

Licensing Triggers

Knowing the common triggers for licensing requirements when exclusions do not apply fosters compliance. Technology transfer offices and faculty should be aware of these triggers and consider them whenever an exclusion is not clearly applicable. Technology licensing staff and faculty should confer with the office having expertise in export controls and responsibility for administering the institution's compliance program and licensing whenever it is possible that a license may be required.

An ITAR license will be required, and likely will be denied (meaning that the export will be prohibited), if the proposed export of an ITAR-regulated defense article (including USML-listed and otherwise regulated materials or items) or related defense service (technical data, training, or instruction) is to an ITAR-prohibited country or a United Nations Security Council arms-embargoed country.[57] Otherwise, a license will be considered and granted or denied on a case-by-case basis.[58] The same analysis applies to deemed exports of controlled technical data/technologies in the U.S.

An EAR license may be required for a proposed export of materials or items (or related technologies or technical data) listed on the CCL under the catchall EAR 99 category, if the export involves an entity or person on the EAR entity list or denied person list, a prohibited end use such as a weapons of mass destruction program, an OFAC-embargoed

country, any other U.S.-embargoed country, or anyone listed on the OFAC prohibited list.[59] Otherwise, no license will be required for EAR 99 listings.[60] An EAR license may be required, and will be considered and granted or denied on a case-by-case basis, if the proposed export concerns CCL-listed materials or items (or controlled technologies or technical data) in CCL categories other than EAR 99, depending on the destination and end user.[61] Licenses may be required under EAR for exports to certain entities or individuals in a country, even when exports to other entities or individuals in the same country do not require a license. Again, the same analysis applies to deemed exports of controlled technical data/technologies in the U.S.

An EAR license is required for the export of most chemicals or biological agents or toxins listed on the CCL for chemical and biological weapons control purposes to any country (even Canada). Such license will be denied (meaning the export will be prohibited) if the proposed export is to Syria or OFAC- or other U.S.-embargoed country or to an end user who is on the EAR denied person list. Otherwise, a license will be considered on a case-by-case basis.[62] An EAR license will be required and likely will be denied (meaning the export will be prohibited) for exports of chemicals or biological agents or toxins listed on the CCL for Chemical Weapons Convention (CWC) compliance purposes, including for Ricin D and E and Saxitoxin, to any country that is not a party to CWC.[63]

Compliance Program

The technology transfer office's role in an institution's administration of export controls and embargoes should be made clear in the institution's compliance program. Will the office rely on the faculty or a central expert office to determine the applicability of export controls and exclusions? Or, is the technology transfer office to serve as a gatekeeper for one of the portal's through which transfers of controlled materials or items and related information constituting controlled technologies and technical data may occur?

Regardless of the answer to that question, there are some steps that the technology transfer office should take to support an institution's export compliance program. Material transfer agreements and technology licenses should contain a general requirement that the parties will comply with U.S. export controls and embargoes to the extent

applicable and that performance of the agreement is subject to such compliance. If a license is required for a particular transfer, the technology transfer office should ensure that the operative technology transfer agreement also identifies the license and that the terms of the transfer comply with the license terms and conditions. To eliminate the continuation of contracts that cannot be performed, the termination provision of these agreements should provide for termination rights if export/embargo compliance (e.g., a required license) cannot be secured or maintained. It is also prudent for such agreements to require the transferor of materials or items or technology to notify the transferee if these are export-controlled and to require the written consent of the proposed transferee prior to making the transfer. This approach supports better identification of incoming controlled materials or items and controlled information.[64]

Current Challenges and Developments

One of the important current issues under OFAC regulations concerns scholarly publications involving foreign nationals. In a September 2003 OFAC ruling concerning the Institute of Electrical and Electronic Engineers Inc. (IEEE), OFAC found that IEEE's peer review and style and copy editing of scholarly articles submitted for publication by nationals of OFAC economically sanctioned countries (Iran, Cuba, Libya, and Sudan) may constitute prohibited services under the International Emergency Economic Powers Act (IEEPA) and the Trading with the Enemy Act (TWEA).[65] This ruling caused considerable concern in the publishers' industry and in the scholarly community whose free and collaborative development and dissemination of research underlie the nation's strength in higher education, innovation, and the global economy.

In an April 2, 2004, letter, R. Richard Newcomb, director of OFAC, clarified OFAC's position in a manner that limits the effect of OFAC's September 2003 ruling.[66] Newcomb applies the so-called Berman Amendment, section 1702(b)(3) of IEEPA and Appendix, Section 5(b)(4) of TWEA, to exclude from OFAC regulation (but not necessarily from EAR or ITAR regulation, which must be separately evaluated) "any information or informational materials, including but not limited to, publications, films, posters, phonograph records, photographs, microfilms, microfiche, tapes, compact disks, CD-ROMs, artworks, and news wire feeds" in any "format or medium of transmission" where the information

or informational material is "fully created and in existence" and there is no "substantive or artistic alteration or enhancement of the information or informational material." The director's letter provides further guidance on the scope and terms of what are permissible peer review and style and copy editing.

By notice in the Federal Register on December 17, 2004, OFAC amended its sanctions regulations at 31 C.F.R. 515 (Cuba), 538 (Sudan), and 560 (Iran) to issue new general licenses authorizing certain activities related to paper or electronic publishing of "manuscripts, books, journals and newspapers" (written publications) with individuals and entities in Cuba, Sudan, and Iran, where the activities would not otherwise be permitted under the sanctions as involving already fully created "information or informational materials."[67] The revised regulations and general licenses supercede the OFAC director's letter and permit individuals and entities subject to U.S. jurisdiction to "[c]ollaborate[] on the creation and enhancement of written publications...[a]ugment[] written publications through the addition of items such as photographs, artwork, translation, and explanatory text...[s]ubstantive[ly] edit[] written publications [and engage in] [o]ther transactions necessary and ordinarily incident to the publishing and marketing of written publications..." among other activities.[68] Although it is not free from doubt or explicitly stated, "collaborating" on the "creation" of written publications would arguably permit a U.S. citizen to co-author an article with a national of Cuba, Sudan, or Iran, particularly where "substantive" editing is separately authorized under the licenses. Clearly a U.S. citizen may substantively edit and enhance the article or other written publication of a national of Cuba, Sudan, or Iran.

The new regulations list certain proscribed activities that are not covered by the general licenses, including any activity that is "not necessary and ordinarily incident to the publishing and marketing of written publications...;" the "development, production, design or marketing of software;" and any activity controlled under EAR or ITAR.[69] Transactions relating to written publications and any kind of substantive editing or joint authorship of written publications that are not authorized as already fully created information or informational materials are still prohibited with the governments of Cuba, Sudan, and Iran. For purposes of the general licenses, these governments include their respective political

subdivisions and individual representatives. Academic and research institutions and their personnel, however, are not deemed to be a part of these governments, even if they are public institutions.[70]

Note that these revised OFAC regulations only address written publications with authors who are nationals of Cuba, Sudan, and Iraq. There are other countries subject to OFAC sanctions today, and the list is constantly changing as U.S. foreign policy changes with world events. Would the same scope of activities with authors who are nationals of other sanctioned countries be permissible, or at least would the more limited peer review and copy and style editing of articles be permissible under the rationale set forth in the OFAC director's April 2004 guidance? Arguably, under the OFAC director's April 2004 letter, at least the more limited peer review and copy and style editing of scholarly journal articles are permitted respecting authors of Libya, another OFAC-sanctioned country, as limited and described in the OFAC director's letter. OFAC implies that, in its view, substantive editing and creation or co-authorship of articles with nationals of OFAC-sanctioned countries other than Cuba, Sudan, and Iran, are not permitted without a specific OFAC license because there are no general licenses applicable to these activities. The new regulations are more lenient about the scope of permissible activities than is the OFAC director's guidance (presumably because the regulations actually provide a license for certain activities). The law is unclear at best. It is hoped that the OFAC may promulgate additional licenses in the future. If not, the issues are likely to remain in the forefront as the publishing and scholarly communities are likely to assert freedom to create, review, and edit scholarly publications with foreign colleagues.

Note also that export controls must still be assessed to determine whether information shared or created with a foreign national constitutes controlled technical data or technology and requires a license under EAR or ITAR, even if the OFAC general license described above applies to the same information. This assessment should be completed before information is shared with a national of a foreign country (whether as a co-author or someone whose work is being peer-reviewed or edited), on a subject that may be export-controlled to avoid an unintentional violation of the export regulations.

Conclusion and Resources

Export controls are a complex regulatory scheme. They are increasingly the focus of law enforcement efforts to defend the country from terrorist threats, whether or not they are effective for this purpose in our global world of easy Internet access for purchasing and communications. Research universities are at the center of this focus. For more information about export controls and embargoes, and exclusions and exemptions from controls, refer to the resources at http://web.mit.edu/srcounsel/71 and at http://web.mit.edu/osp/ including:

- *Deemed Exports for Faculty Members and Senior Research Staff,* Massachusetts Institute of Technology, http://web.mit.edu/srcounsel/resource/Deemed_Export_Information_September.pdf, http://web.mit.edu/osp/www/resources_export.htm
- *Export Controls (EAR/ITAR) and Embargoes (OFAC) Requirements and Exclusions,* http://web.mit.edu/srcounsel/resource/AppendixI.pdf
- *Export Controls and Embargoes Country Key,* http://web.mit.edu/srcounsel/resource/AppendixG.pdf
- *Export Controls of Chemicals and Bio-Agents/Toxins,* http://web.mit.edu/srcounsel/resource/AppendixH.pdf

Also refer to *Export Controls and Universities: Information and Case Studies,* published by the Council on Governmental Relations, and to the report, *Restrictions on Research Awards: Troublesome Clauses, A Report of the AAU/COGR Taskforce* by Julie T. Norris, Office of Sponsored Programs, MIT, at http://www.aau.edu and http://www.cogr.edu.

Notes

1. See Commerce Control List, infra note 17, and U.S. Munitions List, infra note 23.
2. BPARA, Pub. L. No. 107-188, 116 Stat. 594 (2002). See also "Anti-Bioterrorism Laws that Affect Technology Transfer at Academic Institutions" in this publication.
3. USA PATRIOT Act, Pub. L. No. 107-56, 115 Stat. 272 (2001) (to be codified in scattered sections of 5, 8, 12, 15, 18, 20, 21, 22, 28, 31, 42, 47, 49, 50 U.S.C). See also

Jamie Lewis Keith, "Anti-Bioterrorism Laws that Affect Technology Transfer at Academic Institutions" in *AUTM Technology Transfer Practice Manual,* 3rd ed. (Northbrook, IL: Association of University Technology Managers, 2006), Vol. 1, Pt. 1, Ch. 9.

4. Biological research (including research in biological sciences, medical sciences, other life sciences, and biological and biomedical engineering) has grown at a rate of 97 percent over the ten years ending in 2001, as compared with all other areas of scientific research and development which grew at a rate of 55 percent, according to a National Science Foundation survey. And these fields continue to be among the most productive in academic research today. See *National Science Foundation, Academic Research and Development Expenditures, 2001,* available at http://www.nsf.gov/sbe/srs/rexp/start.htm (lasted visited Apr. 4, 2004).
5. See 15 C.F.R. § 764.3 (2004) (providing civil and criminal penalties for willful violation of the Commerce Department's EAR); 22 C.F.R. § 123.1 (2000) (requirement for export or temporary import licenses).
6. See http://www.bxa.doc.gov/licensing/ExportingBasics.htm; http://web.mit.edu/osp/www/OSP_Booklet_2005/index.html.
7. Criminal penalties for willful violations under the Commerce Department's EAR are up to $250,000 and/or up to ten years imprisonment for each violation for individuals, and up to the greater of $1,000,000 or five times the value of the export for entities, depending on when the violation occurred. 15 C.F.R. § 764.3(b). Civil fines are from $10,000 to $100,000 per violation depending on when the violation occurred and the classification of the goods or technology involved. The Commerce Department can assess multiple violations per shipment. Id. § 764.3(a). Criminal penalties assessed against individuals and entities for willful violation of the State Department's ITAR are up to $1,000,000 and/or up to ten years imprisonment for each violation. 22 U.S.C. § 2778(c) (2000). Civil fines are up to $500,000 per violation. Id. § 2778(e). Criminal penalties for violation of OFAC's regulations are up to $1,000,000 in fines for entities and $250,000 in fines for individuals, along with the potential for up to ten years of imprisonment. 31 C.F.R. § 515.701 (2003). Civil fines are up to $55,000 per violation. Id.

8. ITAR, 22 C.F.R. §§ 120-130; EAR, 15 C.F.R §§, 730-774; and OFAC, 31 C.F.R. § 500. Refer to resource materials available at http://web.mit.edu/srcounsel/ and at http://web.mit.edu/osp/, to *Export Controls and Universities: Information and Case Studies,* published by the Council on Governmental Relations, and to the report, *Restrictions on Research Awards: Troublesome Clauses, A Report of the AAU/COGR Taskforce"* by Julie T. Norris, Office of Sponsored Programs, MIT, at http://www.aau.edu and http://www.cogr.edu.
9. See, e.g., 15 C.F.R. § 730.6 (national security, foreign policy, nonproliferation, and terrorism); 15 C.F.R. § 742.3(b)(viii)(A) (Nuclear Non-Proliferation Treaty).
10. For example, the State Department regulates the sending or taking of a defense article out of the United States or disclosing technical data to a foreign person whether in the United States or abroad. 22 C.F.R. § 120.17(1), (4). The Commerce Department regulates actual shipments out of the U.S. as well as a release of technology or source code subject to the controls in a foreign country, or to a foreign national in the United States. 15 C.F.R. § 734.2(b)(1)-(2).
11. 15 C.F.R. § 764.3(a)(2).
12. 15 C.F.R. §§ 730-774.
13. 50 U.S.C.A. §§ 2401-2420 (2003 & West Supp. 2003). The Export Administration Act has lapsed. Its provisions are being implemented through Executive Order.
14. E.g., Executive Orders under the International Emergency Economic Powers Act, id. §§ 1701-1706 (2003).
15. 15 C.F.R. § 734.2(b).
16. Id. §§ 730.1-730.3, 730.5-730.7, 734, 772, 774, Supp 1 and 2.
17. See id. § 774 [hereinafter Commerce Control List].
18. 22 C.F.R. §§ 120-130.
19. 22 U.S.C.A. § 2778 (1990 & West Supp. 2003).
20. 22 C.F.R. § 120.1.
21. See id. § 120.17, 120.19 ("export" and "reexport," respectively).
22. Id. § 120.3(a)-(b). See also id. § 120.6 ("defense article"), § 120.9 ("defense service"), 120.10 ("technical data").
23. Id. § 121.1 [hereinafter U.S. Munitions List].
24. See id.

25. See id. § 121.15 (vessels of war and special naval equipment, including all submarines designed, modified, or equipped for military purposes).
26. Id. §§ 121.1, 120.3(b).
27. See id. § 120.3 (policy on designating and determining defense articles and services, including those that are specifically designed, developed, configured, adapted, or modified for a military application, which do not have predominant civil applications as well as those with significant military or intelligence applicability); id. § 121.1, at Category XVI: Nuclear Weapons, Design and Testing-Related Items.
28. See 31 C.F.R. § 500 (2003).
29. Id.
30. 31 C.F.R. § 500 et seq. The particular sanction for each embargoed country establishes the scope of the prohibitions.
31. See 15 C.F.R. 772, 774, Supp. 1 and 2; 22 C.F.R. § 120.10 ("technologies" and "technical data"). See 15 C.F.R. § 772, 774; 22 C.F.R. 120.10 ("use"). The regulatory definition of "use" under EAR lists "operation, installation...,repair,...and refurbishing," among other activities, as "use," literally requiring all of the listed activities to be conducted to constitute "use." However, the Commerce Department's interpretation may differ from the literal words.
32. See 15 C.F.R. § 734.2.
33. Id.
34. See 22 C.F.R. § 120.17 ("export"), 120.19 ("reexport"), § 120.10 ("technical data"), 120.9 ("defense service"); 15 C.F.R. § 734.2(b). Note that traveling abroad with a computer on which EAR- or ITAR-regulated encrypted software code is loaded may be an export. See 15 C.F.R. § 734.2.
35. See 15 C.F.R. § 734.2; 22 C.F.R. § 120.17(2)-(5) ("deemed exports") and 15 C.F.R. § 772, 774, Supp. 1 and 2; 22 C.F.R. § 120.10 ("technologies" and "technical data"). There are some limitations on transfers of certain ITAR-controlled materials or items in the U.S. For more information on deemed exports, see the guidance for researchers at http://web.mit.edu/srcounsel/resource/Deemed_Export_Information_September.pdf or http://web.mit.edu/osp.

36. The State Department regulates the sending or taking of a defense article out of the U.S. or disclosing technical data to a foreign person whether in the U.S. or abroad. 22 C.F.R. § 120.17(1), (4). The Commerce Department regulates actual shipments out of the U.S. as well as a release of technology or source code subject to the controls to in a foreign country or to a foreign national in the United States. 15 C.F.R. § 734.2(b)(1)-(2)(2004).
37. See Country Control Chart, 15 C.F.R. § 738, Supp. 1 (2004).
38. See supra note 36 and accompanying text.
39. See 15 C.F.R. 734.3(b)(1)(v); 15 C.F.R. 734.10(b); 22 C.F.R. 125.2(b).
40. See 22 C.F.R. § 123.6 (2003); 15 C.F.R. § 740.1(f).
41. 31 C.F.R. § 500 et seq.
42. See http://www.treas.gov/offices/enforcement/ofac; http://www.ustreas.gov/offices/eotffc/ofac/sdn/index.html; http://www.ustreas.gov/offices/eotffc/ofac/sanctions/index.html.
43. See http://www.fas.org/irp/offdocs/nsdd-189.htm.
44. In a November 2001 letter to Dr. Harold Brown, co-chairman of the Center for Strategic & International Studies, Dr. Condoleezza Rice, assistant to the President for National Security Affairs, stated, "the policy on the transfer of scientific, technical, and engineering information set forth in NSDD 189 shall remain in effect, and we will ensure that the policy is followed" while a "broad-based review" ensues of "technology transfer controls." See http://www.aau.edu/research/Rice11.1.01.html. Dr. Rice, in an October 2004 letter to then MIT president Charles M. Vest and twenty-one other research university presidents, confirmed the importance of both fundamental research and security. See http://web.mit.edu/srcounsel/resource/Condoleezza_Rice_Letter.pdf.
45. 15 C.F.R. § 734.3(b)(3), 734.8(a),(b); 22 C.F.R. § 120.11(8).
46. The limited exception relates to an expanded "fundamental research" exclusion involving research satellites and related information exports to government research institutions and to universities in European Union countries, NATO countries, major non-NATO allies, and European Space Agency countries where only nationals of these countries will have access. See 22 C.F.R. 121.1 XV(a) or (e), 123.16(b)(10)(equipment), and 125.4(d)(services/information/instruction).

47. See 15 C.F.R. 734.8(b); 15 C.F.R. 734.11; 22 C.F.R. 123.16(b)(10)(ii). EAR provides a limited exception from licensing requirements when the federal government imposes specific national security controls in a funding contract provided that the university adheres to all of the national security controls. These controls are typically as or more stringent than the security that would have to be implemented in connection with an export licenses. If the controls are not satisfied, export-licensing requirements apply (and a violation will arise if a license was required and not obtained) and the fundamental research exclusion is not available.
48. The report, *Restrictions on Research Awards: Troublesome Clauses,* of a joint task force of the Association of American Universities and the Council on Governmental Relations issued in March 2004 finds that over a six-month period (August 2003 through February 2004), the twenty institutions participating in the task force experienced 138 instances of publication or foreign national restrictions being imposed by federal funding agencies on unclassified federally funded research. This report is available on COGR's Web site at http://www.cogr.edu and on AAU's Web site at http;//www.aau.edu. The task force was headed by Julie T. Norris, then director of MIT's Office of Sponsored Programs, who also authored the report, and included representatives of California Institute of Technology, Carnegie Mellon University, Duke University, Georgia Institute of Technology, Harvard University, MIT, Northwestern University, University of Pennsylvania, Stanford University, Texas A&M, University of California at Berkley and San Diego, University of Cincinnati, University of Colorado at Boulder, University of Maryland at College Park, University of Michigan, University of Minnesota, University of Texas at Austin, University of Wisconsin, and Washington University in St. Louis. The restrictions sometimes were imposed directly in an award to a university and other times were passed through a prime commercial company awardee to a university under a subcontract. A minority of schools accepted the restrictions as initially imposed, a minority of schools declined the funding, some schools negotiated changes in the conditions to eliminate unacceptable restrictions (although the negotiations took many months and delayed the research), and some schools were still negotiating at the time of the report. In accepting these types of restrictions, institutions accept the application of export controls and corresponding fundamental changes to campus openness and nationality blindness in the related research. If export controls apply to research, foreigners

cannot participate or an export or deemed export license must be obtained and/or other requirements satisfied, and security measures must be implemented to ensure that foreigners do not have access to the controlled research except as permitted under the license and other controls.

49. See 15 C.F.R. § 734.8(b)(2)-(3). ITAR does not provide specific guidance on this point, but prevailing wisdom applies the same guidelines to both regulatory schemes.
50. See 15 C.F.R. § 734, Supp. 1 (2004), at Section D: Research, Correspondence, and Informal Scientific Exchanges, Question D(7) and Answer.
51. See 15 C.F.R. § 734.8(b)(4)-(5); 22 C.F.R. § 120.11(8). It is best to use controlled sponsor proprietary information only at the sponsor's site if possible. This places the primary burden for securing the information from unlicensed disclosure to foreign nationals on the sponsor. Note, however, that a faculty member who is permitted under the sponsor's license or because he or she is a U.S. citizen to have access to the controlled information and who takes notes on or acquires the controlled information at the sponsor's site, must take care to secure the notes and to not disclose the information to foreign nationals in violation of applicable licenses and controls. If the university will accept this information, appropriate security must be implemented to prevent an unauthorized deemed export in the U.S. or an export abroad.
52. 22 C.F.R. §§ 120.10-120.11.
53. 15 C.F.R. §§ 734.3(b)(3), 734.7.
54. The acceptance of any of these restrictions also will result in the invalidation of the fundamental research exclusion under ITAR at 22 C.F.R. § 120.11(8) and EAR at 15 C.F.R. § 734.8, although, under EAR, the acceptance of national security controls in government sponsored research that is solely subject to EAR may qualify for a licensing exemption under 15 C.F.R. § 734.11.
55. Information in the "public domain" and "publicly available" is outlined in ITAR under 22 C.F.R. § 120.11 and § 120.10(5). Information in the "public domain" and "publicly available" is outlined in EAR under 15 C.F.R. § 734.3(b)(3) and §§ 734.7-734.9. Information on export controls on patent applications can be found at 22 C.F.R. § 125.2(b) and 15 C.F.R. § 734.10 (EAR), as well as 37 C.F.R. § 5 (Secrecy of Certain Inventions and Licenses to Export and File Applications in Foreign Countries). Web

sites are clearly an authorized means of publication under EAR and are probably an acceptable means of publication under ITAR, although there is no formal guidance on this point from the Department of State.

56. 15 C.F.R. §§ 734.3(b)(3), 734.7.
57. 22 C.F.R. § 126.1. See http://web.mit.edu/srcounsel/resource/AppendixG.pdf and http://web.mit.edu/srcounsel/resource/AppendixI.pdf for a current listing (subject to change) of such countries.
58. 22 C.F.R. § 120.20.
59. 15 C.F.R. § 732.3.
60. See, e.g., 15 C.F.R. § 732.3(d)(5) and following General Prohibitions. See also http://web.mit.edu/srcounsel/resource/AppendixG.pdf and http://web.mit.edu/srcounsel/resource/AppendixI.pdf for a current listing (subject to change) of such countries.
61. 15 C.F.R. § 732.1.
62. See 15 C.F.R. § 738, Supp. 1; 15 C.F.R. § 774, Supp. 1, at 1C 351-54. See also 70 Fed. Reg. 19688 (April 14, 2005) (expanding CB controls of equipment used in biological research).
63. See 15 C.F.R. § 742.18 (License required for export to non-Chemical Weapons Convention country, unless an end user certificate is issued by the governments of all importing countries). If an item or technology is listed for CWC compliance purposes, as well as chemical and biological weapons control and/or antiterrorism purposes, the license requirements for all such listing purposes apply. 15 C.F.R. § 774, Supp. 1, at 1C 355 (regarding CWC), 1C 350 (regarding precursors for toxic chemicals); 15 C.F.R. § 738, Supp. 1 at 1C 355 (regarding weapons control and antiterrorism). See http://web.mit.edu/srcounsel/resource/AppendixG.pdf and http://web.mit.edu/srcounsel/resource/AppendixI.pdf for a current listing of CWC countries and http://web.mit.edu/srcounsel/resource/AppendixH.pdf for a chart on export control of chemicals and biologicals (all subject to change).
64. An example of an export controls and embargoes provision is: "Notwithstanding any other provision of this Agreement, it is understood that the Parties are subject to, and shall comply with, United States laws, regulations, and governmental requirements and restrictions (a) controlling the export of technology, technical data, com-

puter software, laboratory prototypes and other commodities, materials, information and items (individually and collectively, "Technology and Items") and/or (b) restricting or prohibiting entering into certain transactions and providing services or anything of value to certain sanctioned countries, individuals and entities ("Transactions and Services"), including without limitation, the Arms Export Control Act, the Export Administration Act of 1979, relevant executive orders, regulations under those Acts and orders, and the United States Treasury Department's embargo and sanctions regulations and requirements, all as amended from time to time (collectively, "Restrictions") and that the parties' obligations hereunder are contingent on compliance with applicable Restrictions. The transfer of any such Technology and Items and the entering into and provision of such Transactions and Services that are subject to Restrictions (x) may require a license or authorization from the cognizant agency of the United States, and/or (y) may require written assurances by the receiving party that it shall not re-export such Technology and Items to certain foreign destinations and/or to certain recipients without prior approval of the cognizant government agency, and/or (z) may require that the involved individuals and entities comply with conditions and/or prohibitions relating to such Technology and Items and/or Transactions and Services. The securing of any such license or authorization cannot be guaranteed, although the Parties shall make reasonable efforts and cooperate in pursuing such license or authority.

Before any Party may provide any Technology and Items and/or enter into or provide Transactions and Services that are subject to Restrictions to or with any other Party, the providing Party shall request the agreement of the receiving Party and the receiving Party shall agree in writing to receive the Technology and Items and/or to enter into the Transactions and Services, as the case may be. Before any Parties engage in any activity that is subject to Restrictions, all participating Parties in such activity shall have explicitly acknowledged the application of such Restrictions in writing. Each Party shall notify all of the other Parties of the name and notice information for its representative for purposes of giving and receiving notices, agreements, and acknowledgements concerning Items and Materials and Transactions and

Services that are subject to the Restrictions. [University]'s person for such notices, agreements and acknowledgements is [University]'s Director, Office of [___], and [____]'s person for such notices, agreements and acknowledgements is its Director, Office of [____]."

65. See http://www.ustreas.gov/offices/eotffc/ofac/legal/statutes/ieepa.pdf (IEEPA) and the Trading with the Enemy Act, http://www.ustreas.gov/offices/eotffc/ofac/legal/statutes/twea.pdf (TWEA). See OFAC press release at http://www.ustreas.gov/press/releases/js1295.htm.
66. See http://www.treasury.gov/offices/eotffc/ofac/actions/index.html.
67. 69 Fed. Reg. No. 242, 75468-75472 (December 17, 2004); see the revised general licenses that are codified at 31 CFR 515.577 (for Cuba), 31 CFR 538.529 (for Sudan), and 31 CFR 560.538 (for Iran).
68. 31 CFR 515.577(a)(1)-(7), 538.529(a)(1)-(7), and 560.538(a)(1)-(7).
69. See 31 CFR 515.577(b), (c) and (d), 538.529(b), (c) and (d), and 560.538(b), (c), and (d).
70. See 31 CFR 515.577(a), 538.529(a), and 560.538(a).
71. Portions of other publications of the author are included in or have been adapted for this chapter.

The World Trade Organization and Intellectual Property

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The World Trade Organization (WTO) was formed in 1995 and has its headquarters in Geneva, Switzerland. However, its roots are older and go back to the General Agreement on Tariffs and Trade[1] (GATT), which was adopted after World War II.

The negotiations that led up to the adoption of the GATT during 1947 were intended as a precursor to a more general treaty on international trade, the negotiations for which started on November 21, 1947, and led to the completion of the Havana Charter in the following year. Had the Havana Charter ever come into operation, it would have created an international trade organization under the auspices of the United Nations. Although various portions of what was agreed at Havana have come into operation separately since that time (for example, United Nations Conference on Trade and Development code on restrictive trade practice), the Havana Charter as such never came into effect, principally as a result of the reluctance of the US Senate to ratify the charter to set up an international organization controlling world trade.

The original GATT itself was never ratified by the US Senate either. This caused some questioning by academics at various times as to whether the United States is, in fact, legally bound by the general agreement. The accepted view, however, is that the United States' adherence to the original GATT was a legitimate exercise of presidential authority under the terms of the Reciprocal Trade Agreement Act of 1934 as extended by the Trade Agreement Extension Act of 1945. The GATT was amended several times, for example, at Annecy, France, in 1949; at Torquay, England, in 1951; and, since then, at Geneva in 1956; and in negotiations from 1960 to 1961 (the Dillon round), from 1964 to 1967 (the Kennedy round), and from 1973 to 1979 (the Tokyo round). The early revi-

sions all focused on tariff and access issues. However, by the time of the Tokyo round, the idea of broadening the scope of the agreement started to come under consideration.

Detailed considerations of all of the provisions of GATT would be out of place here. Certain provisions should, however, be noted. Firstly, Article 1 established a general most-favored nation treatment between member states. This provides that, for custom duty and the like, any advantage favor, privilege, or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties.

Article 9 essentially applied this most-favored nation concept to marking requirements as indications of origin and contained an interesting proviso that whenever it is administratively practical to do so, contracting parties should permit any required marks for origin to be fixed at the time of importation.

Article 11 essentially banned quotas and other forms of limitations on importation except for duties, tariffs, taxes, or other charges.

Article 23 provided that any member state that believed that it has been unfairly discriminated against by another member state and that the party against whom the complaint was made had failed to abide by its obligations under the treaty can refer to the matter for consideration to the entire body of contracting parties. This was submitted to a panel for consideration, and the panel was then supposed to report back to the members of GATT as a whole on its findings. Ultimately, if it was concluded that there had, in fact, been a breach of the treaty, then the treaty members acting as a body might authorize the country to suspend the application to any other contracting party or parties of such concessions or other obligations under this agreement as they determine to be appropriate under the circumstances. There was, however, significant scope for delay and pressure might be brought even to prevent a panel report being considered by the treaty members as a group.

Attempts at revision were made during the Tokyo round of negotiations in the late '70s. It was agreed that the objective of the dispute-settlement procedure should be to achieve a mutually acceptable solution between the parties. It is only when conciliation failed that the formal dispute mechanism came into operation.

Another major difference between the Tokyo round and previous rounds was that, for the first time, discussion began to focus on nontariff barriers. There had been some discussions of these during the Kennedy round negotiations, but nothing had come of them. The negotiations during the Tokyo round on nontariff barriers led to a whole clutch of new subsidiary agreements including those on subsidies and countervailing duties, on customs valuation, on import licensing procedures, on government procurement, and on technical barriers of trade. It also resulted in an amendment to the antidumping code.

The Uruguay Round

During the early 1980s, there was a growing consensus that a significant amount of business had been left unfinished in the Tokyo round. Pressure thus began to build for convening of a further round of negotiations. In particular, there was pressure to expand the focus of GATT to cover trade-in services as well as goods and for further revision of the dispute settlement procedures. This led to the start of a further round of negotiations for revision of GATT called the Uruguay round as a result of its initial conference having been held in Punta del Este in 1986.

All this was happening just after attempts had been made to achieve amendments to the Paris Convention for the Protection of Industrial Property, the treaty that provides the basis for international cooperation for patents and trademarks. One of the proposed amendments was to expand Third World countries' rights to impose compulsory licenses on patentees.[2] This proposal was resisted strongly, initially only by American industry but subsequently by the Europeans. The resistors ultimately prevailed at a conference in Nairobi in 1981, thwarting this attempt but resulting in deadlock on all other issues as further proposals for amendment of the Paris convention seemed unlikely to come forward for many more years.

This, nevertheless, turned senior management's attention to intellectual property matters and their relationship to international law. In general, such managements were more familiar with GATT than with the World Intellectual Property Organization. Thus, a momentum began to build for incorporating some provisions relating to intellectual property into the next round of GATT negotiations. A further advantage of incorporating intellectual property issues into GATT, unlike the Paris convention, includes means for taking action against countries that do not comply with the obligations. Learning from its experiences in connection with the proposed Paris convention amendments, American industry early on sought to enlist the assistance of European industry so that by the time the agenda for the next round of GATT negotiations was being drawn up, governments on both sides of the Atlantic were under pressure from industry to address intellectual property. Despite substantial resistance from certain Third World countries (most notably India and Brazil), this pressure was successful in having intellectual property incorporated into the agenda for the Uruguay round.[3]

The Uruguay round resulted in a diplomatic conference in Marrakech that established a formal world trade body, known as the World Trade Organization (WTO).[4] Unlike the original proposal of the Havana Charter, however, this body is not affiliated with the United Nations, a fact that enables territories such as Hong Kong, Macao, and Taiwan that are not members of the United Nations to be full participants in WTO.[5]

WTO is governed by a Misterial Council that meets at least once every two years. Subordinate to this is a General Council that meets more frequently and is composed of permanent ambassadors to Geneva, and below this are other more specialized councils including an Intellectual Property Council. Decisions are typically taken by consensus. The WTO secretariat is a purely administrative body with no decision-making authority of its own.

In addition to creating the WTO as a body, the Uruguay round also effected a number of changes to the GATT[6] itself, now confined to dealing with issues relating to trade-in goods, and added a new agreement on trade-in services (General Agreement on Trade in Services[7]) and codes on a number of issues including Trade Related aspects of Intellectual

Property (TRIPs)[8] and a new dispute settlement code.[9] All of these agreements apply to all WTO members; indeed, it was only as a result of concessions gained from the developed world in totally unrelated areas that developing countries agreed to the incorporation of TRIPs in the final package of agreements that concluded the Uruguay round. It is not possible to pick and choose between them. Although the primary impact on intellectual property was affected by TRIPs, the changes in dispute settlement are also important.

The background to the adoption of the TRIPs agreement and, in particular, its imposition of minimum standards for intellectual property protection after WIPO had failed to achieve amendment to the Paris convention, initially led to some tension between WIPO and the WTO on intellectual property issues. An agreement between the two bodies was eventually reached that came into effect on January 1, 1996.[10] Under this agreement, the two bodies agreed to share information and try to avoid duplication of efforts.

A further round of negotiations for revision of the WTO and the agreements related to it was commenced in 2001 at Doha in Qatar.[11] Few intellectual property issues were on the agenda, but where the current round of negotiations may result in changes, this will be noted in the discussion of the relevant provision of TRIPs. The most significant issues under consideration are the interrelationship of the patent system with the need to provide access to pharmaceuticals to deal with health-care crises in the developing world, the possible creation of an international register for geographical indications of origin, and of a higher degree of protection for geographical indications of origin, and a review of the provisions of TRIPs relating to the patentability of plants and animals. As discussed below, in 2003, the TRIPs council agreed that for pharmaceutical products required to deal with a health crisis, there could be a waiver of a requirement that had confined the grant of compulsory licenses to what was required to supply a domestic market, thereby allowing the use of compulsory licenses to provide for supply of drugs to other countries where a health crisis exists. This provision was made permanent by an amendment to the TRIPs agreement that was adopted by the General Council of the WTO on December 6, 2005.

The Agreement on Trade Related Aspects of Intellectual Property

The WTO created by the Uruguay round of negotiations for revision of GATT came into operation on January 1, 1995. With certain exceptions, the TRIPs agreement relating to intellectual property matters came into effect one year later on January 1, 1996.

The agreement has five substantive parts:

- General Provisions and Basic Principles
- Standards Concerning the Availability, Scope, and Use of Intellectual Property Rights
- Enforcement of Intellectual Property Rights
- Acquisition and Maintenance of Intellectual Property Rights and Related Inter-Partes Procedures
- Dispute Prevention and Settlement

Additional parts deal with transitional provisions, which will be dealt with when discussing the relevant substantive provisions and institutional arrangement.

General Principles

Part 1 of TRIPs sets out general principles that include a requirement that all members of TRIPs shall comply with Articles 1, 2, and 19 of the Paris convention, [2] although it does not require TRIPs members to become members of the Paris convention and not all countries that are members of TRIPs have in fact joined the Paris convention. The TRIPs agreement also specifically adopts the national treatment requirement of the Paris convention and adds to this a most-favored nation provision requiring member countries to treat nationals of all WTO-member states no less favorably than it treats its own nationals or nationals of any other country.[13]

It is of interest that this section also contains a specific statement that, as long as the principles of national treatment and most-favored nation treatment are applied, nothing in it shall be used to address the issue of exhaustion of intellectual property rights.[14]

Part II of the TRIPs agreement provides for minimum standards of substantive law for "the Availability, Scope, and Use of Intellectual Property Rights." There are subparts relating to each of the major rights, namely:

- Copyright and Related Rights[15]
- Trademarks
- Geographical Indications
- Industrial Designs
- Patents
- Layout Designs (Topographies) of Integrated Circuits
- Protection of Undisclosed Information
- Control of Anti-Competitive Practices in Contractual Licenses

We will consider these in turn.

Substantive Provisions Relating to Copyright

The major provisions of TRIPs in the field of copyright protection include the following:

1. An obligation to comply with the provisions of Articles 1–21 and the appendix to the Berne Convention for the Protection of Literary and Artistic Works, coupled with an express statement that "copyright protection shall extend to expressions and not to ideas, procedures, methods of operation, or mathematical concepts as such."[16]
2. A requirement to treat computer programs, whether in source code or object code, as literary works for copyright protection purposes and to provide protection for databases if their selection or arrangement "constitute intellectual creations" without prejudice to any copyright subsisting in the data or material itself.[17]
3. A requirement to give to authors of computer programs and cinematographic works and producers of phonograms the rights in certain circumstances to control commercial rental of the originals or copies of their works.[18]
4. An obligation that, in respect of works other than photographs and works of applied art, the normal duration of copyright protection shall be at least fifty years from the death of the author.[19]

5. An obligation to limit fair-use provisions and similar conditions on the exercise of copyright to "certain special cases which do not conflict with normal exploitation of a work and do not unreasonably prejudice the legitimate interests of the right holder."[20]
6. Obligations to afford, subject to conditions, limitations, exceptions, and reservations permitted by the Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, certain minimum rights for the protection of performers, producers of phonogram, and broadcasting organizations. For performers, this protection is against fixation of unfixed works, reproduction of any such fixation, and unauthorized broadcasting of their performance. The protection has to last for at least fifty years from the end of the calendar year in which the performance took place. For phonogram producers, the protection is against direct or indirect reproduction of their phonograms and has to last for at least fifty years from the end of the year in which fixation took place. Broadcasters have the right to control fixation or rebroadcasting of their works and are to have the right to control such acts for at least twenty years from the end of the year of the broadcast.[21]

Substantive Provisions Relating to Trademarks

Major provisions of GATT relating to trademarks are:

1. Any visually perceptible sign (including those consisting of letters, numerals, and colors) that is capable of distinguishing goods or services of one party from goods of another shall be regarded as being capable of functioning as a trademark and registerable as such. Member states are, however, free to refuse registration of signs that lack inherent distinctiveness, unless those signs have acquired distinctiveness through use.[22]
2. Registration may be conditioned on the mark being used. However, actual use must not be a prerequisite for filing an application for registration.[23] Nor shall an application be refused simply because an intended use has not commenced within three years of the application date.[24]
3. The Paris convention provisions relating to protection of well-known marks must apply to marks used in respect of services as well as goods.[25]

4. Limitations on the rights conferred by trademark protection, such as fair use of descriptive terms, must take account of the legitimate interests of the trademark owner and third parties.[26]
5. Countries that provide for cancellation of registrations on the ground of nonuse must allow a period of nonuse of at least three years without a valid reason for the nonuse before such provisions may be invoked. Certain excuses for nonuse outside the trademark owner's control, such as import restrictions and other government requirements, are to be recognized as valid reasons for nonuse. Furthermore, third-party use under the control of the owner of the mark shall inure to the benefit of the owner of the mark.[27]
6. Encumbrances on the use of a trademark (such as requirements that its use must be linked with some other mark) are barred.[28]
7. Although member countries may impose conditions on the terms under which trademarks may be licensed, compulsory licensing of trademarks is banned as are prohibitions on the right of a trademark owner to assign a trademark without transfer of the business to which the mark belongs.[29]

Substantive Provisions Relating to Geographical Indications

Under the TRIPs agreement, member territories are required to make provision for interested parties to prevent use of a designation that falsely indicates the geographical origin of goods if this is done in a way that misleads the public as to the geographical origin of the good in question and to prevent or cancel registration of a trademark if this would have a similar effect.[30] More specific provisions were agreed for wines and spirits, which called for the establishment of a multilateral system for notification and registration of geographical indications for wines.[31] The TRIPs agreement called for further negotiations on this subject to enable increased protection for geographical indications of origin.[32]

Substantive Provisions Relating to Industrial Designs

Articles 25 and 26 provide that member territories must provide for protection of new and original independently created industrial designs for a period of at least ten years. There is, however, no need to provide protection for a design dictated essentially by technical or functional considerations. Such protection may be by way of industrial design law

or copyright and must provide protection against articles embodying a copy or a substantial copy of the protected design.

Substantive Provisions Relating to Patents

Nondiscrimination in Patent Protection

In the patent field, two potential issues of discrimination arise, having regard to the nature of the invention and having regard to the circumstances of the invention. Discrimination on both counts is forbidden.

Firstly, it is provided that patents shall be available and enjoyable without discrimination as to the place of invention,[33] the field of technology, and whether the product is imported or produced locally. (The first of these requirements necessitated a change in 35 USC 104 to prevent discrimination against inventions made abroad.[34])

Secondly, it is provided that the only types of inventions that countries can exclude from patentability are (a) those whose exploitations would prejudice public order or morality; (b) those involving diagnostic, therapeutic, or surgical methods for the treatment of humans or animals; (c) plants and animals; or (d) essentially biological processes for the production of plants or animals.[35] Countries taking advantage of the provision to preclude the grant of patent for new plants must, however, provide some alternative means of protection for such plants.[36]

Finally, it is provided that patent rights shall be enjoyable without discrimination as to whether products are imported or locally produced.[37]

Limitations on Rights and Compulsory Licensing

Countries are permitted to allow limited exceptions from patent enforcement, for example, experimental-use or personal-use rights that exist in some countries. Article 30 specifically provides that any such rights must not unreasonably conflict with a normal exploitation of a patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account the legitimate interests of third parties.

Compulsory licenses or other "official licenses" are only to be permitted after consideration of the individual situation in which such a license is requested. Any such license shall be nonexclusive and assignable only with the business that enjoys its use and, except in cases of national emergency, the requester of the license having made efforts to obtain a voluntary license on reasonable commercial terms.

Such licenses are also subject to the following:

- They are to be authorized predominantly for supply of the domestic market in the country authorizing the license.
- The license being terminated if the circumstances leading to its grant have ceased and are unlikely to recur.
- The holder of the compulsory license pays adequate compensation for its right to use the invention.
- Determination of the amount of adequate compensation is subject to independent review.
- Where such a license is granted in order to enable use of subsequent patented invention that such a license shall only be granted if the later invention is "an important technical advance of considerable economic significance" relative to the dominant patent and the owner of the dominant patent is entitled to a cross license under the secondary patent.[38]

The health crisis resulting from the spread of AIDS, malaria, and tuberculosis in many of the world's poorest countries has led to a re-evaluation of the need for compulsory licensing in the pharmaceutical field. A ministerial declaration issued at the November 2001 meeting in Doha also pointed out that, in conditions where a health crisis exists, a number of options that are fully compatible with TRIPs remain open to countries to address the situation including

- Applying the customary rules of interpretation of public international law, so that each provision of the TRIPs agreement shall be read in the light of the object and purpose of the agreement as expressed, in particular, in its objectives and principles.
- Granting compulsory licenses and determining the grounds upon which such licenses are granted.

- Determining what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
- Establishing its own regime for exhaustion of intellectual property rights (i.e., allowing of parallel imports) without challenge, subject to the most-favored nation and national treatment provisions of TRIPs.

Subsequently, on August 30, 2003, the member states agreed to a waiver of the requirement that compulsory licenses should be granted only for domestic use, this being the result of an increasing realization that some of the countries that were facing a health crisis had no practicable way of manufacturing the drugs needed themselves.[39] This waiver was converted into a permanent amendment to TRIPs by the WTO General Council on December 6, 2005. This amendment takes the form of the addition of a new article to TRIPs and a separate annex and appendix to TRIPs. [40]

Minimum Duration

The minimum duration of a patent is to be twenty years from its filing date.[41] A footnote notes that, in cases where there may be continuing applications, this may be calculated from the date of the original application. The transitional provisions require that any patent still in effect at the date when a country becomes fully bound by TRIPs shall have this term also.[42]

Reversal of the Burden of Proof

A requirement for reversal of the burden of proof in patent infringement trials involving patents granted for processes, so that there shall be a presumption that a product that could have been made by the process was made by the patented process if either (a) the product itself is new or (b) there is a substantial likelihood that the product was made by the patented process and reasonable attempts made by the patentee have been unable to find out exactly what process was used (few foreign countries have discovery proceedings similar to those available to parties in US litigation so that obtaining proof of infringement of a process patent is often very difficult in foreign countries).[43]

Minimum Rights

Provision is made for a definition of the minimum rights to be granted by a patent as follows: "where a patent is for a product the patentee must have the exclusive right to prevent third parties from acts of making, using, offering for sale, selling that product or importing the product for any of these purposes; and where the patent is for a process, the patentee must have the exclusive right to prevent third parties from an act of using, offering for sale, selling or importing for such purposes at least the product obtained directly by that process." [44]

Substantive Provisions Relating to Topography of Integrated Circuits

Member territories are required to provide protection for the design of integrated circuits as set out in Articles 2–7 (except for Article 6(3) and Articles 12 and 16(3) of the Treaty on Intellectual Property in Respect of Integrated Circuits) and additionally to grant protection for semiconductor chip design for a period of at least ten years from filing an application for protection or from first commercial exploitation, whichever first occurs.[45] The provision also provides that there shall be a limited defense for "innocent" infringers and that the most of provisions relating to compulsory licensing of patents shall apply to integrated circuit designs as well.[46]

Substantive Provisions Relating to Undisclosed Information

Member territories are required to provide protection for "undisclosed information." Such protection must be for information that is secret (i.e., is not "as a body or in the precise configuration of its components generally known or readily accessible to persons within the circles that normally deal with the kind of information in question"), has commercial value because it is secret, and has been the subject of reasonable steps by its owner to keep it secret. Qualifying information must be protected against use by others without the consent of the owner if this use is contrary to honest commercial practices, including use by third parties if they knew or were grossly negligent in not knowing that the information in question had been obtained dishonestly. Member territories must also take adequate steps to protect the confidentiality of data about new chemical entities submitted to government authorities in pursuit of an application to market pharmaceutical or agrochemical products.[47]

Substantive Provisions Relating to Contractual Licenses

The TRIPs agreement recognizes that territories may have a legitimate interest in seeking to prevent inclusion of anticompetitive terms in intellectual property licenses, exclusive grant backs, prohibitions on challenges to validity, and coercive package licensing being given as examples. Territories whose nationals or domicilaries are affected by such provisions are, however, to have a right to be consulted on the application of the law containing such prohibitions to its nationals or domicilaries.[48]

Enforcement of Intellectual Property Rights

As noted above, Part III of the TRIPS agreement sets out provisions relating to the enforcement of intellectual property rights. After setting out some general principles in Article 41, separate sections deal with civil and administrative procedures and remedies,[49] provisional remedies,[50] special requirements for border measures,[51] and criminal procedures.[52]

The general obligations include those of ensuring that enforcement procedures as specified are available to permit effective action against any of the intellectual property rights covered by TRIPs, including expeditious remedies to prevent infringement and act as a deterrent to infringement, that enforcement procedures should be fair and equitable, that decisions on the merits of a case should "preferably be in writing and reasoned" and based only on evidence on which the parties were offered an opportunity to be heard, and that there should be an opportunity for judicial review of administrative decisions and at least of the legal aspects of initial judicial decision.

Procedural Issues

A number of provisions deal with procedural issues.[53] The basic objective is to provide fair and equitable procedures for the enforcement and acquisition of intellectual property rights that are not unnecessarily complicated or costly or entail unreasonable time limits or unwarranted delays.[54] It is required that decisions are preferably in writing and reasoned and that they are based only on the evidence on which the parties were offered the opportunity to be heard. In pursuance of the need for fairness and equity, for example,

Article 43 requires member states to provide means whereby under appropriate circumstances, a judicial tribunal can order production of evidence (something that used to be virtually impossible in Germany or Japan). Production of such evidence is, however, subject to taking steps to protect confidential information so that this provision may prove less useful than it appears. Nevertheless, the agreement does require that, in cases where a party fails to produce information as ordered, the costs courts must be able to decide the proceeding against the offending party.

Minimum Remedies to Be Available

The agreement sets out a minimum set of remedies that should be available to the intellectual property right owner against an infringer. Thus, Article 44 requires member countries to provide for the grant of injunctions to "order a party to desist from infringement" and, in particular, to prevent "entry into the channels of commerce" of imported goods that infringe an intellectual property right. Article 45 specifically provides that damages awarded for infringement of an intellectual property right must be "adequate to compensate for the injury" suffered and that the judicial authorities must have the right to award attorney fees to an intellectual property rights holder who proves that his or her rights have been infringed. Article 46 requires that additionally "in order to create an effective deterrent to infringement," the judicial authorities in member countries must have the right to order disposal of infringing goods and "materials and implements the predominant use of which has been the creation of infringing goods" outside the channels of commerce, or in most cases, the destruction of infringing goods.

Provisional Remedies

A requirement is provided for improving the availability of provisional remedies.[55] The agreement specifically provides that judicial authorities must have the authority to act promptly to prevent infringement from occurring and/or for preservation of evidence and, in appropriate circumstances, to act even without giving the alleged infringer the right to be heard. In such cases it is, however, necessary that the unheard party be given an early opportunity to challenge any remedy that has been ordered. Such remedies may be subject to the right holder having to indemnify any party who has been wrongfully enjoined or restrained.

Special Requirements Related to Border Measures

Countries that are members of TRIPs are, unless they are members of a customs union that makes imposition of border measures impracticable, required to set up procedures to enable trademark and copyright owners to lodge applications to prevent impartations of counterfeit trademark goods or pirated copyright goods.[56] To invoke such a provision, the right holder will have to establish a prima facie case of infringement of its rights and provide a sufficiently detailed description of the goods to the customs authorities so as to make the infringing goods readily recognizable. The right holder may be required to provide a security or equivalent assurance to protect the importer in case of error and to prevent abuse. If this is done, then the customs authorities shall hold the goods for a period of ten working days after the rights holder has been given notice that they are being held to give the right holder the opportunity to commence proceedings for infringement.

Criminal Procedures

Member states are required to provide for criminal procedures and penalties at least in cases of trademark counterfeiting and copyright piracy on a commercial scale.[57] The available remedies must include imprisonment and/or monetary fines "sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity."

Acquisition and Maintenance of Intellectual Property Rights and Related Inter Partes Procedures

A single article[58] requires that member states "shall ensure that procedures for grant or registration (of intellectual property rights requiring such grant or registration) ... permit the granting or registration within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection. The same article also requires that procedures used in granting or registering rights or in administrative revocation procedures should comply with the principles of fairness and equity set out relating to enforcement noted in "Procedural Issues" above. In particular, it is required that any decisions made by an administrative body relating to refusal or revocation of intellectual property rights shall be subject to review by a judicial or quasi judicial authority.

Dispute Settlement under the WTO

Dispute resolution under the WTO is confined to disputes between member territories about the compliance with their obligations under the agreements administered by the WTO.[59] The ultimate sanctions that the WTO can impose if it is found that a territory is in breach of its obligations are confined to the field of international trade, but could, for example, include an authorization to the territory that was harmed by the breach to impose additional tariffs on goods or services coming from the territory that was in breach of its obligations.

A criticism of the old procedure for dispute settlement as it existed under GATT before changes were effected by the Uruguay round was that, because of the lack of fixed deadlines, a country that had been charged with breaching the GATT rules could delay proceedings excessively. Under the current procedure, the objective is to complete the basic dispute resolution proceeding (without appeal) within one year of a complaint.[60]

Prior to the institution of formal proceedings, the rules provide for a sixty-day consultation period within which the parties in dispute are required to discuss the alleged breach of the WTO rules and seek to resolve the dispute amicably.[61] If this does not occur, a panel of experts, normally agreed upon by the parties to the dispute, is set up under the auspices of the General Council (which also acts as the formal dispute settlement body).[62] Normally, there are three experts on a panel, but occasionally this is increased to five. The panel is required to make a decision on the merits of the case within six months of its being appointed.[63] Typically, there are two hearings of the parties and any other government that wishes to comment and there may be a further hearing if expert testimony is needed.[64] Once this is done, a draft of the facts and arguments submitted by the parties is submitted to them for comment. Once such comments have been received, a draft of the full report, including findings and conclusions, is sent to each side.[65] After comments on this have been received, a final report is prepared. In appropriate cases, the report may make recommendations as to how any breach in the rules that it has found may be corrected. This final report is submitted by the panel to the General Council acting as the dispute settlement body.[66] The report then becomes the ruling of the dispute settlement body unless rejected by a consensus within sixty days. Either party is entitled

to appeal against such a final ruling to an appeal panel, typically three members of a permanent seven-member appellate body.[67] This panel is required to give its opinion within a maximum of ninety days. This opinion is then given to the General Council acting as the dispute settlement body, which must either accept it or reject it by consensus within thirty days. Once a decision is final, the territory that was found to be in breach will be subject to strong pressure to amend its law or practice to comply with the ruling. If this cannot be done immediately, the parties to the dispute must discuss reasonable compensation for the aggrieved party. Only if such procedures fail, may the aggrieved party seek authorization for imposition of trade sanction. Wherever possible, such sanctions should be confined to the same sector as that in which the dispute arose.

Aid to Developing and Least-Developed Countries

Article 66 and 67 of TRIPs call for developed countries to encourage technology transfer to least-developed territories and for the developed countries to assist both developing and least-developed countries in implementing the terms of the TRIPs agreement. The least-developed countries have put the question of improving technology transfer to them on the agenda for the current round of negotiations for the revision of all of the WTO-based agreements (the Doha round).

Implementation of TRIPs

The TRIPs agreement came into effect on January 1, 1996. Some of the basic provisions became binding on all WTO members on that date. Some leeway was, however, given so that developing nations were given until January 1, 2000, to implement other aspects of the agreement[68] and a further five years to expand patent protection to all areas of technology.[69] Least-developed countries were given ten years to implement many aspects of the agreement other than the general principles noted in "General Principles."[70]

In the United States, the necessary changes in law to implement TRIPs were effected by the Uruguay Round Amendments Act.[71] Major changes in patent law required were effected by a change in the term of patents from the old term of seventeen years from grant to a new one of twenty years from the filing date,[72] a change in the patent law to permit evidence of inventions made in other WTO member territories to be used when

contesting who invented something first under the United States first-to-invent doctrine.[73] In the field of copyright, copyright protection of certain works that were in the public domain either as a result of never having had copyright protection in the United States or as a result of protection having lapsed for certain reasons was restored.[74] Other changes related to rental rights in computer programs[75] and to various aspects of the protection of sound recordings.[76] In trademark law, the period of nonuse that had to elapse before a mark could be regarded as abandoned was extended from two years to three,[77] and definition of marks that are ineligible for registration on the Principal Register was expanded to include geographical indications that are used in connection with wines or spirits and that identify a place other than the origin of the goods.[78]

In other countries, change was slower. For example, Argentina only amended its law to permit patent protection for pharmaceutical compounds on November 1, 2000, and Brazil on May 15, 1997, and India finally amended its law to achieve this only on January 1, 2005.

A number of issues relating to implementation of TRIPs have been the subject of dispute resolution procedures. The issues have included US copyright law as it applies to the playing of broadcast music in stores and restaurants,[79] Canadian patent law as it applies to the stockpiling of generic versions of pharmaceutical products prior to the expiration of patents for such products,[80] the way in which Argentina dealt with confidential information submitted to obtain marketing approval for pharmaceutical and agrochemical products,[81] and the EU's laws as applied to geographical indications of origin.[82] Details of such disputes and their outcome can be found on the WTO's Web site at http://www.wto.org/english/tratop_e/dispu_e/dispu_subjects_index_e.htm#bkmk87.[83]

So far, however, no trade sanctions have been imposed as a result of a territory's failure to live up to its obligations under TRIPs.

Appendix

Disputes under TRIPs

Respondent	Complainant	Subject	Resolution
Argentina	US (May 20, 2000)	Insufficient protection of data submitted for marketing approval applications, failure to protect microorganisms, etc.	Settled by agreement (June 20, 2002)
Argentina	US (May 6, 1999)	Failure to provide effective patent or exclusive marketing rights for pharmaceutical inventions	Settled by agreement (June 20, 2002)
Brazil	US (May30, 2000)	Local working requirements for patent validity	Settled by agreement (July 19, 2001)
Canada	US (May 6, 1999)	Insufficient patent term for "old" patents	DSP* and appeal body found against Canada, Section 45(2) of Canadian patent law was then amended
Canada	EU (December 19, 1997)	(a) Patent law provisions allowing testing of pharmaceutical invention prior to patent expiration (b) Patent law provisions allowing stock piling of product prior to patent expiry	DSP found this to be OK DSP found this to be a violation; no appeal filed. Section 55.2(2) of Patent Act repealed for compliance
Denmark	US (May 14, 1997)	Failure to provide for adequate provisional measures	Settled by agreement (June 13, 2001)
EC	US (June 1, 1999) Australia (April 17, 2003)	Mechanism for protecting geographical indications (a) discriminatory against non-EU indications (b) unfair in allowing protection for geographical indications of origin even if prior trademark registration	(a) DSP found a violation, EU has asked for time to implement (May 19, 2005) (b) DSP found no violation
EC and Greece	US (April 30, 1998)	Broadcasts of copyright motion pictures by Greek television stations	Settled by agreement (March 26, 2001)

Respondent	Complainant	Subject	Resolution
EC and Ireland	US (January 6, 1998)	Inadequate copyright protection	Settled by agreement (September 13, 2002)
EC	Canada (December 2, 1998)	EU supplementary protection certificates violate rule against nondiscrimination on basis of technology	Never proceeded beyond consultation stage
India	US (July 2, 1996) EU (April 28, 1997)	Failure to provide satisfactory interim protection for pharmaceutical inventions after failure of parliament to ratify presidential decree creating exclusive marketing rights and providing for black box filings	DSP found violation; India passed the necessary legislation
Japan	US (February 9, 1996) EU (May 28, 1996)	Inadequate protection for sound recordings	Settled by agreement (February 5, 1997) Settled by agreement (November 17, 1997)
Pakistan	US (April 30, 1996)	Failure to provide satisfactory interim protection for pharmaceutical inventions	Settled by agreement (March 7, 1997)
Portugal	US (April 30, 1996)	Inadequate patent term	Settled by agreement (October 8, 1996)
Sweden	US (May 28, 1997)	Inadequate provisional measures available to protect intellectual property	Settled by agreement (December 11, 1998)
US	EU (January 26, 1999)	Copyright exclusions for playing music in restaurants and businesses (17 USC 110(5))	DSP found no violation in home-style exception but that business exception was a violation of TRIPs; EU requested arbitration to determine the amount of sanctions that could be levied. This was subsequently stayed following assurances that US administration was working with Congress to find a solution. “Mutually satisfactory temporary arrangement” agreed. (June 23, 2003)

Respondent	Complainant	Subject	Resolution
US	EU (July 8, 1999)	Prohibition on registration or renewal of trademark previously abandoned by owner whose business or assets had been confiscated under Cuban law	DSP basically agreed that no violation; on appeal held that the prohibition was a violation of TRIPs requirements for national treatment and granting most-favored nation status to WTO member countries. The EU has repeatedly agreed to the US being given extra time within which to implement the necessary changes.
US	EU (January 12, 2000)	Procedures under Section 337 of Tariff Act alleged to be unfair	Still in consultation stage
US	Brazil (January 31, 2001)	Patent law provisions relating to inventions made with federal assistance alleged to breach TRIPs especially with respect to requirement that manufacture under a license for such an invention should be in US	Still in consultation stage

* Dispute Settlement Panel

1. 55 U.N.T.S. 187, conveniently found at http://www.wto.org/english/docs_e/legal_e/gatt47_01_e.htm.
2. The Paris convention is the grandfather of intellectual property law treaties dating back to 1883. It provides a number of benefits for applicants and is discussed in Chapter 13, "World Intellectual Property Organization," of the *AUTM Technology Transfer Practice Manual, 3rd Edition.* One of its features is to permit compulsory licensing in some circumstances, but following a revision in Lisbon in 1958, such licensing must be nonexclusive in order to avoid putting the exclusive licensee in a stronger position than would be warranted by the circumstances giving rise to the grant of a compulsory license in the first place. Adoption of a provision allowing exclusive compulsory licensing opened the specter of the patent owner itself not being able to sell the patented product in the country and all sales having to pass through a single entity, thereby opening the door to possible cronyism of the worst type.
3. The road to the adoption of TRIPs was a strange one. The road to the Uruguay round negotiations started in Geneva in 1982. However, debates as to what topics would be considered in the round were not resolved until 1986 when negotiations were formally launched at a meeting in Punta del Este in September 1986. Intellectual property was included in the agenda, although this did not prevent the governments of some countries, such as India and Brazil, trying to take it off the agenda. After the initial launch, during 1988-9, the United States and the European Community both put forward detailed proposals for an intellectual property agreement. Other groups (one comprising Australia, Hong Kong, New Zealand, and the Nordic countries and another comprising Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, and Uruguay) put forward alternative, but less-detailed proposals). After this, matters slowed down, and the negotiators failed to reach agreement, not only on matters relating to intellectual property but also on trade in agriculture, textiles, antidumping, and trade-in services. As a result of this, at the end of 1991, Arthur Dunkel, the director general of GATT, was requested to provide draft agreements on all of these topics. This he did. Although his proposals in other areas were subject to further negotiation, in the intellectual property field, despite criticisms from many quarters, no change was made and the final text was

that of the Dunkel draft of 1991. The final agreement was reached in Marrakech in April 1994.

4. 1867 U.N.T.S. 154, 33 I.L.M. 1144 (1994) [hereinafter Marrakech agreement or WTO agreement], conveniently found at http://www.wto.org/english/docs_e/legal_e/04-wto_e.htm.
5. There are today 149 member territories of the WTO and 32 observers. In general, observers must commence negotiations to become full members within five years of achieving observer status. The most significant territories that are not yet full members, although all are observers, are Russia and several other former Soviet republics, Algeria, Iraq, Libya, and Vietnam. A few countries, including Liberia and Syria, have yet to achieve even observer status.
6. Officially Annex 1A to the WTO agreement, 1867 U.N.T.S. 190, conveniently found at http://www.wto.org/english/docs_e/legal_e/06-gatt_e.htm.
7. Officially Annex 1B to the WTO agreement,1869 U.N.T.S. 183, conveniently found at http://www.wto.org/english/docs_e/legal_e/26-gats_01_e.htm.
8. Officially Annex 1C to the WTO agreement, 1869 U.N.T.S. 299, conveniently found at http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm.
9. Officially Annex 2 to the WTO agreement, conveniently found at http://www.wto.org/english/docs_e/legal_e/28-dsu_e.htm.
10. Agreement between the World Intellectual Property Organization and the World Trade Organization, 35 LLM 754, conveniently found at http://www.wto.org/english/tratop_e/trips_e/wtowip_e.htm.
11. Officially this is known as the Doha Development Agenda, but commonly referred to as the Doha round.
12. TRIPs Article 2.
13. TRIPs Articles 3 and 4.
14. TRIPs Article 6.
15. Some countries, especially those with a civil- as opposed to a common-law tradition draw a clear distinction between what they regard as true copyright (or author's rights) and what are regarded as neighboring or related rights. The latter typically include performer's rights, producer's rights, and broadcasting rights.
16. TRIPs Article 9.

17. TRIPs Article 10.
18. TRIPs Article 11, so far, as cinematographic works are concerned, countries may be excepted from this obligation unless such rental has led to widespread copying of such works that is materially impairing the exclusive right of reproduction conferred in that country on authors and their successors in title. So far as computer programs are concerned, the obligation does not apply where the program itself is not the essential object of the rental, for example, a computer-assisted rental car. The rental right provisions relating to sound recordings are set out in Article 14(4), which applies the provisions relating to computer programs to sound recordings.
19. TRIPs Article 12.
20. TRIPs Article 13.
21. TRIPs Article 14.
22. TRIPs Article 15(1).
23. The 1988 amendments to 15 USC 1051 had already incorporated these features into US law.
24. TRIPs Article 15(3); in the United States, this required a revision of the Lanham Act (15 USC 1127) to change the definition of the term abandoned from a period of nonuse for two years to a period of three years.
25. TRIPs Article 16(3).
26. TRIPs Article 17.
27. TRIPs Article 19.
28. TRIPs Article 20.
29. TRIPs Article 21.
30. This provision led to an amendment of 15 USC 1052 to provide that a mark should not be registered on the Principal Register if it is "a geographical indication which, when used on or in connection with wines or spirits, identifies a place other than the origin of the goods and is first used on or in connection with wines or spirits by the applicant on or after one year after the date on which the WTO agreement ... enters into force with respect to the United States."
31. TRIPs Article 23.
32. These negotiations started before the opening of the Doha round but have now been incorporated into them, together with negotiations for the creation of the registry

for designations of origin for wine. The agenda for the Doha round calls for negotiations for broadening the scope of the provisions for wine and spirits to other products. So far, however, there has been little progress toward an agreement, with Argentina, Australia, Canada, Chile, Colombia, Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, New Zealand, Panama, Paraguay, the Philippines, Chinese Taipei, and the United States taking the position that no change is required and Bulgaria, the EU, Guinea, India, Jamaica, Kenya, Madagascar, Mauritius, Morocco, Pakistan, Romania, Sri Lanka, Switzerland, Thailand, Tunisia, and Turkey taking the view that greater protection for geographical indications is needed.

33. The word invention is not defined as such. Article 27 provides that patents shall be available for "any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application." A footnote states that the terms inventive step and capable of industrial application may be deemed by a member state to be synonymous with the terms *nonobvious* and *useful*, respectively. However, the reference to areas of technology and the use of the term industrial application have led many countries to conclude that there is no requirement under TRIPs to provide for protection of certain types of subject matter that are patentable in the United States such as business methods.
34. TRIPs Article 27(1).
35. Considerations that may be relevant to the ordre public and morality exclusions include exceptions "to protect human, animal, or plant life or to avoid serious prejudice to the environment." There are few cases where the significance of these provisions have been considered. Perhaps the best known is the European Patent Office's consideration of the Harvard Oncomouse, a mouse genetically engineered to render it susceptible to cancer and, thus, useful as a research tool for testing anticancer drugs. In that case, the ultimate holding was that, as long as the definition of the animal was restricted to a mouse (originally the claim had been to any mammal containing the relevant genes), the morality requirement was complied with because the object was to save human life, the genes were only inserted into animals that were kept in research laboratories and were unlikely to be released into the general environment, and by having mice that were particularly susceptible to cancer, one could

reduce the total number of animals that needed to be tested, thereby reducing the pain and suffering of the mouse population as a whole.

36. TRIPs Articles 27 (2) and (3); developing countries were, however, given a five- or ten-year period within which to phase in this provision provided that they adopted interim procedures for permitting the filing of applications for patents for pharmaceutical and agricultural chemical products whereby such applications could be held in suspense until the law changed to permit the patenting of such products, but the applications retained their original filing dates and provision for a limited form of marketing exclusivity up to the time when a patent was granted for such a product. Countries opting for this delay in providing full patent rights for pharmaceutical and agricultural chemicals were, however, obligated to provide for exclusive marketing rights for those who have filed a patent application in the country, secured grant of an equivalent patent in another country, and obtained marketing approval for the product in that country (see Articles 70(8) and 70 (9)). At the WTO Ministerial Meeting in Doha in November 2001, the period within which the least-developed developing countries had to implement fully the requirements for granting patents for pharmaceutical and agricultural chemical products was extended to January 1, 2016. The Doha Ministerial Conference also addressed the provision of Article 27(3) of TRIPs that provides for a review of the provisions relating to protection for plants and animals and expanded the remit of this review to look generally at the role of patents in protection of biodiversity, traditional knowledge, and folklore. Comments submitted as part of this review can be found at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm. A key issue under consideration is the relationship of TRIPs and other treaties relating to patents and the Rio Convention on Biodiversity. The United States is not a party to the Rio convention. One particular point of focus is whether patent applicants should be required to disclose the country of origin of genetic material or traditional knowledge incorporated in their applications so that such countries can ensure that there was informed consent from the groups supplying such material so that they can receive fair compensation as called for by the Rio convention The view that this should be a requirement is being pushed by Brazil, India, Bolivia, Colombia, Cuba, Dominican Republic, Ecuador, Peru, Thailand, and is supported by the African group. However,

other views have been expressed, for example, by the EU, that any disclosure requirement should be outside the patent system and the United States, that such matters are best dealt with by national legislation and contract. It seems unlikely that the issue will be resolved soon.

37. TRIPs Article 27(1).
38. TRIPs Article 31.
39. See Decision of the General Council of August 30, 2003, which can be found at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.
40. The revision will come into force when ratified by two-thirds of the membership of the WTO. The Hong Kong meeting that adopted the amendment set a target date of December 1, 2007, to achieve these ratifications. The United States has already done so. Details of acceptance of the new provision can be found at http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm. Article 31 bis provides that the requirement that a compulsory license should be granted only for the predominant purpose of satisfying the domestic market "shall not apply" if the product in question is a pharmaceutical product "to the extent necessary" to address the public health problems noted in the 2001 declaration and that adequate remuneration for the production shall be paid to the patent owner in the exporting country. The annex sets out the procedure to be followed requiring, inter alia, that the country wishing to import the product has advised the TRIPs council and, if not a least-developed nation, confirms that it is unable to produce the relevant product itself in sufficient quantities to deal with the problem. The grant of the license is further to be subject to additional conditions to avoid the possibility of abuse, for example, by requiring special packaging, labeling, coloring, or shaping of products supplied under this arrangement "provided that such distinction is feasible and does not have a significant effect on price." Details of the arrangements can be found at http://www.wto.org/english/news_e/news05_e/trips_decision_e.doc.
41. TRIPs Article 33; this required an amendment of 35 USC 154 to change the term of a US patent from the traditional term of seventeen years from grant to twenty years from filing. As a byproduct of this change, the United States introduced provisional patent applications that could form the basis of a subsequent nonprovisional application, as long as the latter was filed within twelve months of the former. The twenty-

year term then starts from the filing of the nonprovisional application. The thinking was that, since foreigners can delay for a year from filing an initial application in their own countries before filing in the United States, this gave them the possibility of an effective twenty-one year term from that first foreign filing, which would be unfair to US citizens who would file here first. A provisional application cannot claim priority from a foreign application (35 USC 111(b)(7)).

42. TRIPs Article 70(8)(3).
43. TRIPs Article 34; on the question of discovery, see also Articles 43 and 47. Article 43 requires that where a party has presented reasonable evidence to support its claim but needs further specified evidence that is in the control of the opposing party to substantiate that claim, the judicial authorities shall have the authority to order production of that evidence, subject to adequate protection being given to protect confidential information. The treaty does not, however, require that any particular sanction be exercised against a party that fails to comply with such an order. Article 47 states that member countries "may" provide for their judicial authorities to have the right to order an infringer to disclose the identity of third parties involved in production or distribution of infringing goods.
44. TRIPs Article 28; this language is similar to that of Article 25 of the proposed European Patent Convention, which, although it has never come into effect, acted as a model for legislation in many countries. The requirement to give protection is narrower than that set out in 35 USC 271(g), which makes the importation, sale, or offer for sale in the United States of a product made abroad using a process patented in the United States an infringement of the US patent unless the product was materially changed after the step that was covered by the US patent or becomes a trivial and nonessential component of another product. The International Trade Commission has the power to bar the import of any product that was produced abroad by a process covered by a patented process even if a material change has occurred (*Kinik Co* v. *ITC* 362 F.3d 1359, 70 USPQ2d 1300 (Fed. Cir. 2004)).
45. TRIPs Articles 35 and 38.
46. TRIPs Article 37.
47. TRIPs Article 39.
48. TRIPs Article 40.

49. TRIPs Articles 42 and 49.
50. TRIPs Article 50.
51. TRIPs Articles 51 and 60.
52. TRIPs Article 61.
53. TRIPs Articles 42 and 61.
54. TRIPs Articles 41 and 42. Article 62 extends the principles of fair and equitable procedures and, specifically, requirements of no unnecessary complications or costs and no unreasonable time limits or delays to patent prosecution.
55. TRIPs Article 50.
56. Counterfeit trademark goods are defined as "any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation." Pirated copyright goods are defined as "any goods which are copies made without the consent of the right holder or person duly authorized by him in the country of production and which are made directly or indirectly from an article where the making of the copy would have constituted an infringement of a copyright or related right under the law of the country of importation."
57. TRIPs Article 61.
58. TRIPs Article 62.
59. A list of agreements administered by the WTO to which the dispute settlement procedure applies is set out in Appendix 1 to the Dispute Settlement Understanding. It includes TRIPs.
60. Officially this is Annex 2 to the Agreement Establishing the World Trade Organization and is entitled "Understanding on Rules and Procedures Governing the Settlement of Disputes."
61. Dispute Settlement Understanding Article 4.
62. Dispute Settlement Understanding Article 6.
63. Dispute Settlement Understanding Article 12.
64. Dispute Settlement Understanding Article 13.
65. Dispute Settlement Understanding Article 15.

66. Dispute Settlement Understanding Article 16.
67. Dispute Settlement Understanding Article 17.
68. TRIPs Article 65(2).
69. TRIPs Article 65(4).
70. TRIPs Article 66.
71. Pub. L. 103-465.
72. 35 USC 154.
73. 35 USC 104.
74. When implementing the TRIPs agreement, 17 USC 104A "restored" copyright protection (a) where copyright which previously existed in the United States lapsed by failure to comply with formalities imposed by US copyright law, for example, by failure to renew a copyright or failure to comply with provisions previously existing in US copyright law such as a requirement to publish works with a notice or to comply with the manufacturing clause; (b) sound recordings which never had protection in the United States as a result of having been fixed prior to February 15, 1972; (c) works from countries with which the United States did not have copyright relations at the time of the work's publication.
75. The change in respect of protection of computer programs is to abolish the sunset provision that previously existed in respect of rental rights for such programs.
76. So far as sound recordings are concerned, 17 USC 1101 was added to provide federal civil and criminal remedies against those who fix sounds or sounds and images of live musical performances; transmit or otherwise communicate to the public the sounds or sounds and images of a live musical performance; or distribute or offer to distribute or offer to sell, rent, or offer to rent or traffic in any copy or phonorecord fixed as described previously.
77. 15 USC 1127.
78. 15 USC 1052.
79. Dispute No DS 160 brought by the EU. The Dispute Settlement Panel found no violation in homestyle exception of 17 USC 110(5), but found that business exception was a violation of TRIPs. The EU requested arbitration to determine the amount of sanctions that could be levied. This was subsequently stayed following assurances that US administration was working with Congress to find a solution. A mutually satisfactory temporary arrangement was reported on June 23, 2003.

80. Dispute No DS 114 brought by the EU. The Dispute Settlement Panel found this to be a violation. Canada did not appeal and repealed the offending provision (Section 55.2(2)) of its Patent Act.
81. Dispute DS 196, this was settled by agreement between the United States and Argentina without the need for a formal Dispute Settlement Panel finding.
82. Disputes DS 174 brought by the United States and DS 290 brought by Australia; the Dispute Settlement Panel found that the EU's way of registering geographical indications of origin was discriminatory against persons from outside the EU. The EU agreed to amend its procedures, and on May 19, 2005, asked for extra time within which to make the necessary changes.
83. A total of twenty-two requests to institute dispute resolution proceedings have been brought under TRIPs so far (fourteen by the United States and five against the United States). Of these, fourteen were either settled by agreement or never proceeded beyond the consultation stage. Of the others, violations were found in six cases. Two cases are still in the consultation stage. A brief summary of disputes relating to TRIPs that have been referred to the WTO is set out in the appendix to this chapter.

Rights in and Responsibilities for Technical Data and Computer Software under Federal Awards

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Introduction

Many university administrators and technology transfer officers are familiar with the federal rules relating to managing inventions and patents that have been developed in the performance of federally funded research. The Bayh-Dole Act (35 USC Section 200-212) provides a uniform federal regime for rights to inventions under federally funded awards. Unlike rights to inventions, there is no controlling statutory authority for rights to technical data and computer software. In fact, the federal data rules and regulations are inconsistent with the government's approach to invention rights under Bayh-Dole and do not reflect current copyright law or legal developments regarding the patentability of computer software.[1]

In addition to their complexity, the rules often require an institution to take specific steps to retain the maximum rights to data and software developed under federally sponsored projects. Different federal agencies have different regulations and the same agency may have different regulations depending on what type of funding document it issues. A grant or a contract from the same agency will differ in the rules and regulations for the appropriate management, retention of rights, and use of data and software developed under the award.

It is important that research administrators and technology transfer practitioners be familiar with the application of a federal agency's rights in data, technical data, computer software, and copyrights. These rights should be discussed with principal investigators before a response to a federal procurement solicitation or an unsolicited proposal is sent to a federal agency because it is important to identify and protect the rights of the institution and the faculty at the proposal stage. Copyright and license rights to copyrighted material developed under a federally sponsored project are important to the government, the public's right to use federally funded research, authors, and universities.

General

The Federal Acquisition Regulation (FAR) system (48 CFR FAR system) is the primary contracting body of regulations for all federal procurement. Part 27 of FAR, "Patents, Data and Copyrights," prescribes policies, procedures, and directions for use of various contract clauses pertaining to patents and directs agencies to develop their own coverage for rights in data and copyrights. Part 52 of FAR, "Solicitation Provisions and Contract Clauses," contains the basic clauses described in Part 27. Under the authority of Part 27, some agencies, such as the Department of Defense (DOD), Department of Energy (DOE), and National Aeronautics and Space Administration (NASA), have modified the clauses in Part 52 for use in their own contracts. These modified clauses appear in agency-specific parts of FAR. The current version of FAR Part 27 was adopted in 1987.[2]

Under the general FAR provisions followed by the civilian agencies, the government receives an unlimited license to data produced under research contracts. This license essentially enables the government to exercise all the rights of the owner of the data, including the right to reproduce the data, prepare derivative works, distribute copies to the public, and perform and display publicly the data. These broad rights contrast markedly with the far more limited government-use license to inventions under the Bayh-Dole Act. Government approval is needed for funding recipients to claim copyright in the data.

However, FAR permits all contractors to establish copyright in scientific and technical articles published in professional journals that contain data produced in the performance of the contract without government approval. In contracts for basic or applied research performed *solely* by universities and colleges, FAR also allows universities and colleges to claim copyright in *any* data (including computer software) produced under the contract. Included in FAR is a provision that is critical for universities that states that no restrictions may be placed upon the conduct of or the reporting on the results of unclassified research in contracts for basic or applied research with universities or colleges except as otherwise provided in U.S. statutes.

The Defense Federal Acquisition Regulations Supplement allocate rights and responsibilities for the use and protection of data produced under DOD contracts according to the source of funds used for data development. If developed exclusively with government funds, the government is entitled to unlimited rights to the data similar to the approach under FAR. All DOD contractors acquire the same data rights and responsibilities; DFAR makes no special provision for educational institutions. DOE acquisition regulations distinguish legal rights in data under FAR from DOE's contract rights. Where DOE acquires contract rights to data, it requires DOE permission to claim copyright for any computer software produced under the contract. NASA has a restriction similar to DOE for computer software.

In recent years, there has been a trend toward greater uniformity among the agencies in rights to data under federal grant awards. Federal grant recipients generally may copyright any data developed under the award. The federal awarding agency reserves the right to reproduce, publish, or otherwise use the work for federal purposes, more similar to its license right to inventions under the Bayh-Dole Act. The DOE alone among the major research funding agencies has migrated its contract requirements into its grant requirements. However, the DOE generally allows its university grantees to establish copyright in all data produced under the award, including computer software. The ten federal agencies (including DOE) that participate in the Federal Demonstration Partnership (FDP) follow the general government-grant approach to data under the Office of Management and Budget (OMB) Circular A-110 for the ninety-six participating FDP institutions. Some agencies, both in their general grant terms and conditions and FDP agency-specific terms and conditions, have specific requirements for the sharing and dissemination of data produced under their grants.

Definition of Data

For federal agency contracts governed by FAR, the general definition of *data* found in FAR 27-401 and 52.227-14(a), is "recorded information, regardless of form or the media on which it may be recorded." The terms *software* and *technical data* are broadly defined and are subsets of the term *data.* The term includes data to which the copyright laws may or may not apply. Instructions to contracting officers regarding the use of alternate sections contained in Section 52.227-14 are found in Section 27.409.

There is no counterpart federal-wide definition of data for grants. Nevertheless, OMB Circular A-110 (__.36 Intangible Property) sets forth broad government rights to data (see "Rights in Data and Computer Software under Grants and Cooperative Agreements" below). The individual federal granting agencies define data in a variety of ways. For instance, the National Science Foundation (NSF) refers to data in terms of the dissemination of the *results and accomplishments* of the activities of the funded project. The National Institutes of Health's (NIH)definition for data incorporates copyright law and defines data as "recorded information, regardless of form or media on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other research data."

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Rights in Technical Data and Computer Software Are under Government Contracts

Federal Acquisition Regulations provide the basic procurement practices for all executive agencies. Rights in technical data and copyrights (RITD) for civilian agencies are prescribed in FAR Subpart 27.4 and implemented at FAR 52.227.14 through 52.227-20. The DOD has mission and procurement needs that often differ from the government's civilian agencies. DOD RITD are prescribed in the DOD's FAR Supplement (DFARS) at DFAR Subpart 227.71, "Rights in Technical Data," and implemented at DFAR 252.227-7013 through 252.227-7033.

There are fundamental differences between the civilian and the defense agencies regarding implementation of provisions for RITD. FAR 27.402, the policy statement, is the only section applicable uniformly to all executive agencies. Other provisions in Part 27 provide a default when agencies have not adopted separate regulations and describe a basic scheme for use by contracting officers in deciding which clause or parts of clauses to apply in particular situations. Section 27.409, "Solicitation Provisions and Contract Clauses," provides a summary of situations in which the contracting officer is required to include the alternate provisions of Section 52.227-14 as well as Sections 52.227-15 through 52.227-23 in a contract.

As consideration for funding research, the government may acquire or obtain access to many kinds of data produced during or used in the performance of a government research contract. The government's rights may vary, depending either on the statement of work or if the data were developed with mixed government/nongovernment funding. Usually the government receives a royalty-free, nonexclusive, irrevocable worldwide license to all of the bundle of rights protected by copyright. These include the right to reproduce, prepare derivative works, distribute copies to the public, and perform and display publicly the copyrighted data. This unlimited license enables the government to act on its own behalf and to authorize others to exercise the same rights and essentially gives the government all of the rights of the copyright owner.

Part 52 classifies data into four categories reflecting the nature of data and restrictions that apply to them. The defense agencies have their own categories of data. This chapter describes first the basic FAR clauses; then the DOD clauses. Two other agencies, DOE and NASA, follow the basic FAR clauses, but each has its own individual variations discussed in each of its FAR supplements. The discussion on these variations follows the DOD discussion. Finally, this section concludes with discussion of a few special FAR clauses on data rights.

Federal Acquisition Regulations (FAR 52.227-14)

Rights in Data: General

The general rights in data clause is FAR Section 52.227-14. It contains nine sections comprising: Definitions; Allocation of Rights; Copyrights; Release, Publication, and Use of Data; Unauthorized Marking of Data; Omitted or Incorrect Markings; Protection of Limited Rights Data and Restricted Computer Software; Subcontracting; and Relationship to Patents. In addition, five alternates follow the clause describing substitutions or additions to the general clause. Government contracts may cite 52.227-14 with any of the appropriate alternates. Most contracts and subcontracts provide only the citations of the applicable clauses without their actual text. Thus, it is important for university contract administrators to have ready access to the actual language so that they can carefully check the citations in the agreement of this clause and any designated alternate against their needs and expectations. Federal Acquisition Regulations may be found online at http://www.arnet.gov/far/.

Definition of Data under FAR

Section 52.227-14(a) defines data, limited rights data, computer software and restricted computer software as follows.

- *Data* is "recorded information, regardless of form or the media on which it may be recorded." The term *data* includes technical data and computer software. Technical data are defined as "data which are of a scientific or technical nature." Section 52.227-14(a) also defines several categories of data including "form, fit and function" data (data relating to items, components, or processes that are sufficient to enable physical and functional interchangeability, as well as data identifying source, size, configuration, and other characteristics).
- *Limited rights data* (other than computer software) are those that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such data pertain to items, components, or processes developed at private expense, including minor modifications thereof.
- *Computer software* means computer programs, computer databases, and documentation thereof.
- *Restricted computer software* is computer software developed at private expense and that is a trade secret, is commercial or financial and is confidential or privileged, or is published copyrighted computer software.

Types of FAR Data Rights

FAR 52.227-14(a) also identifies several types of data rights. These include:

- *Unlimited rights,* defined as the right of the government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so;
- *Limited rights,* defined as the rights of the government as set forth in a limited rights notice included in paragraph (g)(2) of this clause; and
- *Restricted rights,* defined as the rights of the government in restricted computer software, as set forth in a restricted rights notice as set forth in this clause, or as otherwise may be provided in a collateral agreement, including minor modifications of such computer software.

Nature of Rights to FAR Data

According to Section 52.227-14(b), the government receives unlimited rights to: (1) data first produced in the performance of the contract; (2) form, fit, and function data delivered under the contract; (3) manuals or instructional and training material for installation, operation, or routine maintenance, etc.; and (4) all other data delivered under the contract and not marked with a limited rights or a restricted rights legend.

The contractor retains rights in the data to use, publish, protect, correct, and claim copyright to some kinds of data first produced in the performance of a contract.

The unlimited rights (see definition above) that are granted to the government are not exclusive rights and, therefore, the contractor can assert ownership if Alternate IV to 52.227-14 is included in the contract (Alternate IV is discussed further below) and license any or all of their rights to third parties as well.

Data First Produced or Delivered under a Contract (FAR 52.227.14[c])

Two FAR clauses are important for universities that wish to assert copyright ownership to data first produced, used, or delivered under a contract.

General

The general FAR clause (FAR 52.227-14[c]) states that the contractor may establish, without prior approval from the federal government, copyright in scientific and technical articles if they contain "data first produced in the performance of the contract and [are] published in academic, technical or professional journals, symposia proceedings or similar works" but requires prior express written approval of the contracting officer to establish copyright in all other data.[3] "First produced" means not previously existing in any form, i.e., written text or machine readable software. Agencies may require advance copies of articles intended for publication in academic, scientific, or technical journals or symposium proceedings or similar works for information purposes only. The clause also provides that the contractor shall have the right to use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the contractor in the performance of the contract.

Alternate IV

The general FAR clause contains an Alternate IV, which FAR indicates is to be used in contracts for basic or applied research to be performed *solely* (emphasis added) by universities and colleges (FAR 27.409[e]). It provides blanket permission for universities and colleges to claim copyright without limitation in *any* data first produced in the performance of the contract. When asserting copyright under Alternate IV, universities must acknowledge the government's sponsorship (including the contract number) on any data for which the university is claiming copyright. Alternate IV also allows the contracting officer to include in the contract-specific exceptions to this permission that are not otherwise already contained in the clause.

University administrators should be aware that the basic FAR rights in data clause, together with Alternate IV, is required by Section 27.404(f)(iii) to be used in contracts for basic or applied research to be performed solely by universities and colleges. However, it cannot be used if the purpose of the contract is development of computer software for distribution to the public. When an industrial prime contractor is subcontracting to a university or a university prime contractor is subcontracting to a commercial organization, contracting-officer permission is required before the university or corporate subcontractor can utilize Alternate IV since the university or college then will not solely perform the work.

Perfecting a claim of copyright ownership in data first produced and delivered to the government still obligates the contractor to provide the federal government with a paid-up, nonexclusive, irrevocable worldwide license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the government. If a copyright claim to software first produced and delivered to the government is perfected, the government *does not* have the right to distribute copies of the software to the public. Hence, using the proper clauses to establish copyright ownership, especially to computer software, should be a priority for any university that commercially licenses its federally funded research results. University contracting officers should review government research contracts involving production of software for their commercial potential and assure copyright ownership is properly asserted.

Security Restrictions

The contractor's rights to data as discussed above under the general FAR clause may be limited to the extent the data are subject to federal export control or national security laws or regulations or unless otherwise provided in this paragraph of the clause or expressly set forth in the contract (FAR 252.227.14 [d][1]). A critical provision for universities in this regard is FAR 27.404(g)(2), which states that no restrictions may be placed upon the conduct of or the reporting on the results of unclassified research in contracts for basic or applied research with universities or colleges except as otherwise provided in U. S. statutes. This provision essentially implements National Security Decision Directive 189 (originally issued in 1985 and reaffirmed as official U. S. government policy in 2001). That directive provides that the products of fundamental research at universities and colleges shall remain unrestricted. Such restrictions, however, may be placed on the contractor's rights to use, distribute, and publish data first produced in performance of the contract in other types of contacts and in contracts with contractors that are not colleges or universities.

Universities should be careful to review the full text of the data rights clauses included in their contracts to assure that they do not contain publication restrictions. Acceptance of such restrictions may not only violate the FAR prescription, but may subject the university to export control regulations as the regulations provide that universities lose their exemption for fundamental research if they accept such restrictions on publications (15 CFR 734.8[b]; 22 CFR 120.11[8]).

The inability to place an explicit provision in the contract restricting publication may not be sufficient to enable publication if the contractor is not able to perfect copyright in the data intended for publication. If the university anticipates publication of data that does not consist of scientific and technical articles based on data first produced in performance of the contract or is not intended for publication in sources such as academic, professional, or technical journals, a university should require inclusion of Alternate IV or seek permission to establish, i.e., perfect, copyright at the earliest opportunity. Universities also need to watch for an addition ([d][3]) to section (d) of the basic FAR data rights clause that requires government permission for a contractor to claim copyright or publish computer software (see discussion of DOE and NASA clauses below).

Data not First Produced in the Performance of the Contract (FAR 52.227-14[c][2])

General Considerations

The second major category of FAR data includes items not first produced under the contract but used in the performance of the contract. Such data could have been created outside of federal sponsorship (e.g., under an industrial contract, university funds, etc.), may have been given to the principal investigator by a third party, or may have been created by a project participant who is not an employee of the institutional contractor (e.g., a student as part of his or her coursework.) If data other than FAR data is delivered to the government, copyright protection, ownership rights, and license rights need to be sorted out prior to the data being delivered to the government. The rights of the contractor, the government, and the third party all must be considered.

Permission is needed from the government before a contractor delivers to the government data that are not first produced in the performance of the contract. With agreement from the government, the contractor may not be required to grant the government its unlimited license rights (FAR 52.227-14[b][1]) that are granted to the government for data first produced in the performance of the contract. It is important for institutions that use pre-existing or third-party data (including software) in contract research to ensure that they have the necessary rights to such data that may be embedded in government deliverables. The government thus has negotiated rights to such data.

Limited Rights Data (FAR 52.227.14[a])

Limited rights data means data that either embody trade secrets or are commercial or financial in nature and are confidential or privileged, to the extent such data pertain to items, components, or processes that were developed at private expense. Limited rights data do not include computer software.

At first glance, it may appear that universities will rarely use or deliver limited rights data to the government, because of policies that promote open and unrestricted publication of research results. However, such situations may occur when the university is collaborating

with, or has an industrial subcontractor who is required, by the terms of the contract, to provide the government with such limited rights data. It can also occur where the contract will require use of pre-existing data that is being held confidential in preparation for potential patenting. Use of confidential data developed at private expense and a contract requirement for its delivery to the federal government will require the data to be protected under the limited rights data clauses of FAR. University research administrators must remember this requirement in reviewing proposals and negotiating contracts.

Under FAR 52.227-14(g)(1), limited rights data should not be provided to the government unless Alternate II or Alternate I is cited. Limited rights under Alternate II allows the government to reproduce and use the data within the government, but not the right to manufacture or disclose the data outside the government, except for the specific purposes stated in a limited rights notice that must be affixed to the data or as may otherwise be agreed upon in the contract. However, Alternative I of the FAR clause provides a different set of criteria for the definition of limited rights data, which may enable the contractor to withhold some of those data otherwise to be delivered to the government. This Alternate I definition does not require that the data relate to items, processes, or components developed at private expense; only that the data themselves have been developed at private expense.

If neither Alternates I nor II are cited and the contractor wishes to withhold data that would qualify as limited rights data, the contractor must describe the withheld data and deliver form, fit, and function data (as defined in 52.227-14[a]) in lieu of the limited rights data. There is a confusing loop created by the interaction of subsections g(1) and b(1), but the principle seems to be if the data qualify as either limited rights data or restricted rights data (see discussion below), the contractor should do something to identify and protect them before delivering them to the government. Failure to identify and protect limited rights data or restricted rights data may result in the government acquiring unlimited rights in such data.

Restricted Computer Software (FAR 52.227.14[a])

Restricted computer software is similar to limited rights data except that it pertains only to software. The software must have been developed at private expense and must be a trade secret, commercial, or financial and confidential or privileged. Published computer software is also restricted computer software. Under Alternate III, (g)(3)(iii), software delivered to the government with a copyright notice will be presumed to be published and licensed to the government without disclosure restrictions unless the contractor includes a notice that it is unpublished with rights reserved in the copyright notice. Computer databases are treated as limited rights data rather than restricted computer software.

Prior to delivery of any restricted rights software, the contractor should clearly determine the government's restricted rights as set forth in the applicable FAR clause or in negotiation with the contracting officer. Proper use of the restricted rights clause becomes very important if the statement of work requires the delivery of the industrial partner's copyrighted software or if the university itself is required to deliver copyrighted software it has developed without government funding. A restricted rights notice is required under Alternate III that gives the government specific but more limited rights than the limited rights notice discussed above.

When Delivery of Limited Rights Data May Be Required

Alternates II and III of FAR 52.227-14 enable the government to require delivery of a contractor's limited rights data rather than allowing the contractor to withhold such data. The government may justify disclosure of limited rights data outside the government, despite the limitation on government rights, by stating the purposes for such disclosure. Examples of such purposes are included in FAR 27-404(d)(1). They include use (other than manufacture) by support service contractors, evaluation by nongovernment evaluators, use (except for manufacture) by other contractors participating in the government's program of which the specific contract is a part, emergency repair, or release to a foreign government.

Minor modifications to limited rights data or restricted computer software will not necessarily subject these modifications to unlimited rights to the government even if they are first developed in performance of a government contract. Minor modifications are included in the definition of limited rights data and restricted computer software and, therefore, are subject only to the corresponding limited or restricted rights.

Since the basic Section 52.227-14(g)(i) allows the contractor to withhold delivery of limited rights data and restricted computer software, the contracting officer must initiate negotiation to include the appropriate alternate or modified contract provision to require the contractor to deliver such data or software and to provide necessary rights to the government. Both Alternates II and III specify the minimum rights the government will normally obtain. Greater or lesser rights may be specified by the contracting officer or by agency regulations. Exclusion of alternate or modified clauses at the initial signing of the contract does not preclude the contracting officer from adding them subsequently during performance by modification should it become necessary to require the delivery of limited rights data or restricted computer software. Alternates II and III of FAR 52.227-14 enable the government to require delivery of a contractor's limited rights data rather than allowing the contractor to withhold such data which is permissible under FAR 52.227-14.

Special Clauses under FAR

There are several less frequently used FAR RITD clauses. Several of these clauses may be of general interest and/or of particular relevance to university contractors or subcontractors.

Representation of Limited Rights Data and Restricted Computer Software (FAR 52.227-15)

Inclusion of Section 52.227-15 in a government solicitation may be an indication that the government anticipates the need for delivery of limited rights data or restricted computer software. The clause requests the offerer to identify such data or software in response to the solicitation. Failure to take advantage of this opportunity to protect such data or software at this stage may make it difficult to secure protections during negotiation or performance of the contract.

Rights in Data: Special Works (FAR 52.227-17)

The special works clause at FAR 52.227-17 is required to be inserted in solicitations and contracts primarily intended for the production or compilation of data (other than limited rights data or restricted computer software) for the government's internal use or when there is a need to limit distribution or obtain indemnification for liabilities arising from the use, performance, or disclosure of the data (Section 27.405). Examples are contracts requiring the production of audiovisual works, development of histories of agencies, and surveys of government establishments. Section 27.405 includes a detailed discussion of the use of the clause in the acquisition of existing audiovisual and similar works, existing computer software, and other existing works.

The government acquires unlimited rights under the special works clause to data (including technical data and computer software) delivered under the contract and to data first produced under the contract. Release, distribution, and publication of the data first produced under the contract by the contractor require the government's written permission. Contractors also may not claim copyright ownership to such data without government permission and must indemnify the government for liability that arises out of its publication or use of the data. These provisions are antithetical to the policies of most, if not all, private institutions and often may be forbidden by state laws applicable to public institutions. University contract officers need to be particularly aware of the special works clause and assure they do not inadvertently accept this clause. Occasionally, universities have inappropriately received this clause in research contracts. There is some evidence that federal agencies are increasingly likely to misuse this clause in university contracts. Acceptance of such restrictions would compromise a university's fundamental research exemption under the export control regulations. Use of the clause also violates FAR (27.404 [g][2]), which states that no restrictions may be placed upon the conduct of or the reporting on the results of unclassified research in contracts for basic or applied research with universities or colleges.

Rights in Data: Existing Works (FAR 52.227-18) and Commercial Computer Software (FAR 52.227-19)

Universities less frequently encounter these clauses. The FAR existing works clause is used by the government for acquisition without modification of existing audiovisual and

similar works. It grants the government a nonexclusive worldwide license to reproduce, prepare derivatives, and perform and display publicly on behalf of the government all subject matter called for under the contract. The clause includes an indemnification provision similar to the special works clause, and, thus, is also inappropriate for universities.

FAR 52.227-19 is used by the government to acquire computer programs, computer databases, or documentation thereof, that have been developed at private expense and are held confidentially, as trade secrets, or otherwise confidential or privileged, or, in the alternative, are published and copyrighted. Generally, the government has the right to use, copy, reproduce, modify, adapt, and disclose the software to support service contractors. If the software includes a copyright notice, it is presumed to be licensed to the government for the above uses, unless the contract expressly states otherwise.

Small Business Innovative Research (FAR 52.227-20)

Since universities often participate as subcontractors to small businesses in phases I and II Small Business Innovative Research (SBIR) awards, faculty and administrators should be familiar with the special section of FAR that pertains to rights in data under SBIR programs. FAR 52.227-20 is designed for SBIR programs and is the only data rights clause that can be used in such contracts (Section 27.405 [c]).

The clause recognizes a category of SBIR rights in data, as set forth in an SBIR rights notice. It specifically permits the SBIR company to assert copyright ownership of FAR data created under the project and to submit the data to the government labeled as SBIR data unless the contract specifically states that the data are to be delivered to the government without restriction. In the latter case, it is not considered an outright prohibition against asserting copyright. Rather, it appears in order to force the SBIR company to get permission from the contracting officer to claim copyright. The government's rights in copyrighted data and computer software developed in performance of an SBIR program are identical to government rights in copyrighted data and computer programs under non-SBIR programs.

The delivery of data with the SBIR rights notice limits the government's use and disclosure rights in such data. The government's license is limited to a right to use the data for government purposes, but prohibits disclosure outside of the government, except for disclosure for use by support contractors, for a period of four years after government acceptance of all deliverables under the contract. After the four-year period, the government is relieved of the nondisclosure requirements, but the data remain subject to the government's more limited right to use the data and authorize others to use it only for government purposes.

The subcontracting provision in 52.227-20 is the same as the one in 52.227-14 and requires the contractor to secure rights from its subcontractors as necessary to provide any required rights to the government.

Rights to Proposal Data (Technical) (FAR 52.227-23)

This clause gives the government unlimited rights to all technical data contained in the proposal upon which the contract is based. The contractor must specifically identify all pages that contain confidential information to be exempt from these rights. It is interesting to contrast this approach with the DFARS approach discussed below, which limits the government's rights.

Department of Defense Acquisition Regulations

Unlike the civilian agencies, the DOD was given specific statutory authority to prescribe regulations for the DOD and its contractors for rights in technical data.[4] The current DOD regulations regarding rights in technical data and computer software went into effect in 1995.

Differences between DOD regulations for computer software and other types of technical data are recognized by two separate sections in DFARS (252.227-7014 and 252.227-7013). (For a copy of DFARS, go to http://www.acq.osd.mil/dpap/dars/dfars/index.htm.) There are significant differences between FAR and DFARS with regard to federal rights in data. DFARS makes no distinction between a commercial organization and a nonprofit educational institution: all DOD contractors acquire the same data rights and responsibili-

ties. Unlike FAR, which determine the rights and responsibilities in contract data by the statement of work and deliverables, DOD regulations allocate the rights and responsibilities for use and protection of the data by recognizing the source of funds for data development. In addition, DFARS provides that the standard license rights granted to the government may be modified through negotiations with DOD. In such negotiations, however, the government cannot receive lesser rights than it would under limited rights, which is discussed below.

DOD's Definition and Allocation of Technical Data

DOD procurement regulations, unlike FAR data rights clauses, do not use the word *data.* DOD regulations use the term *technical data,* which is defined as "recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation)" (DFARS 252.227-7013[a][14]). For purposes of this chapter, technical data developed under a DOD contract is referred to as *DOD technical data.*

DOD explicitly relates the allocation of rights to DOD technical data to the "source of funds" used for development of the data. The separate categories are described below. The contractor retains any rights that have not been given specifically to DOD under the regulations. Like FAR, DFARS also states that the contractor cannot, without written approval, incorporate any third-party-owned material among the data to be delivered to the government unless the government receives a license to use the material.

DOD Technical Data Developed Exclusively with Government Funds (DFARS 252.227-7013[b][1])

DOD technical data developed exclusively with government funds means that, in connection with an item, component, or process, the cost of development was paid for in whole by the government or that the development was required for the performance of a government contract or subcontract. When DOD technical data are developed exclusively with government funds, the government is entitled to unlimited rights.

Unlimited rights are rights to use, modify, reproduce, perform, display, release, or disclose DOD technical data in whole or in part, in any manner, and for any purpose whatsoever, and to have or authorize others to do so. Generally, the government's rights extend beyond DOD technical data that have been or will be developed exclusively with government funds. They also cover studies, analyses, test data, or similar data produced for the contract as an element of specific performance; corrections or changes to DOD technical data furnished to the contractor by the government; and publicly available data created by the contractor that contain no restrictions on their further use, release, or disclosure.

When the DOD determines that it is in the government's best interest to relinquish its right to publish DOD technical data to permit public dissemination by the contractor, Alternate I of DFARS 252.227-7013 can be used. Under this clause, the government relinquishes its rights to publish the data if, within twenty-four months after delivery, the contractor publishes the data and promptly notifies the government.

DOD Technical Data Developed with Mixed Funding (DFARS 252.227-7013[b][2])

When DOD technical data have been developed partially with costs not allocated to a government contract, DOD technical data are considered developed with mixed funding. The government has government purpose rights to such data. *Government purpose rights* are less than unlimited rights and are the rights to "use, modify, reproduce, release, perform, display, or disclose technical data within the government without restriction" and outside the federal government for "government purposes." DOD technical data developed or created in part from indirect (facilities and administrative) cost pools are also considered to be developed with mixed funding.

It is important to note that government purpose rights are limited to a five-year period or such other period as negotiated between the government and the contractor. Government purpose rights begin at the execution of the contract or subcontract that required the development of DOD technical data. After the prescribed period, the government receives unlimited rights in DOD technical data. The government will not release DOD technical data during the five-year time period unless the recipient is a

government contractor who requires the use of DOD technical data and has executed a nondisclosure agreement with the government. In such a case, the contractor owning DOD technical data agrees to release the government from liability and agrees to seek relief solely from the party who has improperly used the contractor's DOD technical data that were marked with restrictive legends.

Five years is not a very long time, considering it begins at the start of the contract rather than at the time DOD technical data are created or disclosed to the government. Although the contractor has an exclusive right to use and license others for any commercial purposes during this initial five-year period, first commercialization of DOD technical data may well occur after this period has ended. Therefore, it is important that administrators discuss this provision with faculty. They might also try to extend the government purpose rights period when negotiating a prime federal contract or subcontract if they expect that a longer period may be necessary for the transfer and commercialization of DOD technical data.

It also is important to recognize that government purpose rights, while more limited than unlimited rights, still give the government broad rights. They are not limited to DOD, but can extend to all other government agencies. Government purpose rights also extend to use in government contracts, as indicated above. Thus, while the rights cannot be used for commercial purposes, they can be used for a wide range of government and contractor activities.

DOD Technical Data Developed Exclusively at Private Expense (DFARS 252.227-7013[b][3])

The government has limited rights in DOD technical data pertaining to items, components, or processes developed exclusively at private expense (or created exclusively at private expense when the contract does not involve production of items, components, or processes), provided it is marked with the prescribed limited rights legend. According to the definition provided at 252.227-7013[a][7], costs charged to indirect cost pools are considered private support. The government is entitled to limited rights when DOD technical data are delivered to it. The DOD technical data *must* be marked with the limited rights legend (see "Protection and Management of DOD Technical Data" below).

Limited rights are narrower than both the unlimited and government purpose rights provided to the government when government support or mixed funding is used to create the data. Limited rights under DFARS 252.227-7013(a)(7) allow the government to "use, modify, reproduce, release, perform, display, or disclose these limited rights data within the government." The government cannot disclose DOD technical data outside the government or use DOD technical data for manufacture except in limited situations, for example, emergency repairs.

Specifically Negotiated Rights (DFARS 252.227-7013[b][4])

Alternative specifically negotiated license rights for the government may be negotiated for any of the above three categories of DOD technical data. However, the government cannot receive lesser rights in such negotiation than it would receive under limited rights. The DOD is very prescriptive in its requirements for marking DOD technical data delivered to the government with government purpose rights, limited rights, or specifically negotiated rights. DFARS 252.227-7013(f) sets forth specific legends for each category. Contractors also are required to justify the validity of the restricted marking (252.227-7013[g]). This contrasts with FAR, which prescribes the content of the limited rights notice, but not its placement (FAR 52.227-14[g][2]). See "Protection and Management of DOD Technical Data" below.

Rights in Noncommercial (and Commercial) Computer Software and Computer Software Documentation (DFARS 252.227-7014)

DFARS includes a clause on rights in noncommercial computer software and software documentation. It defines computer software as "computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae and related material that would enable the software to be reproduced, recreated, or recompiled."

Computer software does not include computer databases or documentation. Computer software documentation means owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.

This clause generally provides the same mix of rights and obligations as with DOD technical data. However, it establishes a category of restricted rights specific to computer software that are narrower and more prescriptive than the limited rights to DOD technical data discussed above. Noncommercial computer software is defined as software that does not qualify as commercial computer software under paragraph (a)(1) of the clause. The clause defines commercial computer software and commercial software documentation as that which has been or will be at the time of delivery sold, leased, or licensed to the public.

The category of noncommercial software and software documentation include all of the software and documentation that university contractors typically deliver to the DOD. Universities need to be mindful of the DOD's distinction between commercially and non-commercially available software and documentation when identifying restricted data and software in contract negotiations. The distinction becomes especially important if, later on, a university desires to commercially license software and documentation that have been previously identified in a DOD contract as noncommercial.[5]

The DOD expects to use and license commercially available software and documentation on the same terms and conditions as the general public. DFARS 227.7202-1 provides that commercial computer software or commercial computer software documentation shall be acquired under the licenses customarily provided to the public unless such licenses are inconsistent with federal procurement law or do not otherwise satisfy user needs. It also provides that commercial computer software and software documentation shall be obtained competitively, to the maximum extent practicable, using firm-fixed-price contracts or firm-fixed-priced orders under available pricing schedules. Contractors are not required to furnish technical information related to commercial computer software or commercial computer software documentation that is not customarily provided to the public except for information documenting the specific modifications made at government expense to such software or documentation to meet the requirements of a government solicitation. Contractors also are not required to relinquish to, or otherwise provide, the government with rights to use, modify, reproduce, release, perform, display, or disclose commercial computer software or commercial computer software documentation except for a transfer of rights mutually agreed upon.

There is no clause prescribed for acquisition of commercial computer software in DFARS. DFARS [227.7203-3] provides that the government shall have only the rights contained in the license under which the software was obtained. If the government needs rights not conveyed under the public license, the government must negotiate with the contractor to determine if such rights are available for transfer.

Rights in Commercial Items (DFARS 252.227-7015)

It is sometimes required that a contractor deliver to the government commercially available items, components, or processes. This section sets forth the mutual rights and responsibilities that apply when the government requires and receives delivery of such commercially available data. Delivery of commercial data can occur, for example, when a contractor is modifying or enhancing commercial data, i.e., the specifications of a machine. It is important to note that this section does *not* pertain to computer software (see discussion above).

The term *commercially available* means that the item, component, or process, has been sold, leased, or licensed or has been offered for sale, lease, or license to the public. In such cases, the government obtains the rights to use, modify, reproduce, release, perform, display, or disclose such data only within the government. The government does not obtain the rights to manufacture additional quantities of the commercially available items, nor can the government, without the prior written permission of the contractor, disclose or permit use of the data outside the government except for emergency repairs or overhaul of the commercial items furnished under the contract.

For universities, these provisions are important when they negotiate DOD contracts or when they license to a third party data that were not previously developed with government funds but will be considered commercially available contract data. When these data have either been licensed to a third party or if an offer has been made to license the data, and the data are a deliverable under a DOD contract, both the subsequent license agreement with the third party and the DOD contract need to identify DOD's rights to the commercially available contract data.

The contractor, subcontractor, or suppliers are not required to provide the government with any additional rights beyond those identified above for commercially available contract data. However, if the DOD desires enhanced rights, it may request that the contractor enter promptly into negotiation with the government to determine the transfer of such additional rights. After agreement between the parties, a license agreement, enumerating the additional rights, will be made a part of the DOD research contract.

Rights in Bid or Proposal Information (DFARS 252.227-7016)

In submitting a proposal to the government, a contractor may disclose DOD technical data that is commercially important to it or one of its subcontractors. If this information is sensitive, steps need to be taken to limit the government's rights to use and disclose the proposal data. Proper protection of these data is essential if the proposal data are likely to be included in a future patent application. Unless the contractor takes affirmative steps to mark its proposal data, submission of the proposal or bid offer to the government could be considered a publication under U.S. and foreign patent laws.

When a contractor submits its proposal or bid offer to the DOD, the contractor agrees that the government may reproduce the proposal to the extent necessary for evaluation. However, evaluation of a proposal or bid does not include the right of the government to disclose the proposal, directly or indirectly, to any person who has not been authorized by the DOD to evaluate it. After the government makes an award to the contractor, the government obtains the rights to "use, modify, reproduce, release, perform, display, or disclose information contained in the contractor's bid or proposal within the government" but does not, without written permission from the contractor, have the right to disclose it outside the government.

If the contractor fails to correctly label restricted data or software described in the proposal or if the contractor has previously provided the government with the same data or has provided it to any other third party without restriction, the government acquires unlimited rights in the proposal data and can disclose the data outside of the government without the contractor's approval. The government's internal use or external transfer of the proposal data without restrictive markings also qualifies as a publication under U.S.

patent law. Thus, proper marking of proposal data is extremely important if such data is to become a part of a patent application or is licensed as a trade secret.[6]

Department of Energy Acquisition Regulations (DEAR)

The DOE has traditionally taken the position that its legal rights to intellectual property and software are greater than those of other federal agencies because of DOE's unique mission under the Atomic Energy Act and later legislation. Several years ago, The DOE replaced its "long and short form" rights in data clauses with the general FAR rights in data clause [52.227-14]. The DEAR provisions on technical data and copyright are set forth in DEAR Subpart 927.4 and are available at http://professionals.pr.doe.gov/ma5/MA-5Web.nsf/Procurement/DEAR+927?OpenDocument.

DEAR distinguish the delivery of technical data from rights in technical data. The DOE generally follows FAR with regard to legal rights in data. However, for contract rights, DEAR incorporates FAR additional data requirements clause (FAR 52.227-16). According to FAR 27.409(h), that clause is to be used for contracts involving experimental, developmental, research, or demonstration work other than basic or applied research to be performed solely by a university or college where the contract amount will be $500,000 or less. This clause applies unless all the data requirements are known at the time of contracting and specified in the contract. The clause gives the government the right to order any data first produced or specifically used in the performance of the contract during contract performance or within three years of acceptance of all deliverables, subject to the contractor's rights to withhold limited rights data or restricted computer software. However, DOE also may include a requirement for contractors to license to the government and third parties any limited rights data or restricted computer software (at "reasonable royalties") unless commercial equivalents are readily available (DEAR 952.227-14).

Where DOE acquires contract rights to data, it substitutes its own definitions and modifies the FAR data rights clause to require DOE permission for the contractor to claim copyright ownership in any software first produced in the performance of the contract. DOE also adds (d)(3) to the general FAR data rights clause, specifying that the contractor cannot assert copyright ownership in computer software first produced in the perform-

ance of the contract without prior written permission of the DOE patent counsel. When such permission is granted, the patent counsel must specify appropriate terms, conditions, and submission requirements to assure utilization, dissemination, and commercialization of the data. Similar responsibility is given the patent counsel for protecting disclosure of data for certain statutory programs (DEAR 927.404-70). These provisions are to be applied down through the subcontracting tier. The requirements must be used in conjunction with FAR 52.227-14 Alternative V, which authorizes federal inspection of contractor data for a period of up to three years after completion of the contract, to assure that the government obtains its proper rights. However, DEAR authorizes the use of Alternate IV in contracts for basic or applied research with educational institutions, except where software is specified for delivery or in other "special circumstances" (DEAR 927.409).

Several definitions unique to DOE expand its rights in data produced or acquired under DOE awards. At 927.409(a)(1)(a), DOE adds the term *computer databases* and defines it as "a collection of data in a form capable of...being operated on (or) by a computer." DOE also enhances the definition of *computer software.* Definitions of *limited rights data* and *restricted computer software* follow DOD regulations. These terms define the rights DOE claims in data or software developed at private expense, which embody trade secrets and are commercial or financial, or confidential and privileged. The DOE's definition of *unlimited rights* includes the right to distribute, display, and perform by electronic means.

The Council on Governmental Relations (COGR) interacted extensively with DOE at the time DEAR technical data provisions were revised. As noted, DEAR "authorizes" DOE contracting officers to use FAR Alternate IV (227.14(c)(1) at their discretion. In a letter of clarification to COGR subsequent to issuance of the new DEAR provisions on technical data, DOE was more definitive. The letter stated: "According to the rule at 927.409(a), in contracts with institutions of higher learning, the FAR Alternate IV would normally be used in contracts for research and development. In such instances, the college or university would have the right to copyright all data first produced under the contract. If, however, the contract called for delivery of software, paragraph (c) of the clause at FAR 52.227-14 and (d)(3) would normally be used."

By conceding a class deviation, DOE made an important concession to universities and contractors that conduct federally sponsored research. However, DOE did not define this exception with either a quantifiable standard or with illustrations. DOE was no clearer in its explanatory letter to COGR: "... 'special circumstances' reserves for DOE the ability to use paragraph (d)(3) in other circumstances that merit departure from the general rule. We expect both required delivery to DOE or special circumstances to arise infrequently, and will have to be identified by DOE in advance of contract execution. This will allow the grantee (sic) the opportunity to question departure from the use of Alt. IV. Please recognize that this rule allowing the use of Alt. IV established by DEAR 927-409(a) is the first time this agency has granted any class of contractors the automatic right to assert copyright in computer software first produced in the performance of the contract and restricted the government license in first produced software. In these situations, DOE is relying upon the educational institutions to fulfill this agency's statutory duty to disseminate. Our approach is entirely consistent with the philosophy expressed at FAR27. 404(f) regarding copyrighting of first produced data."

The DOE revised its data rights clauses in an effort to make its procedures consistent with those of other federal agencies and the existing FAR clauses. However, due to DOE's insistence on greater rights under the Atomic Energy Act and later legislation, its contractors still face more restrictive provisions than under other agency contracts. DOE's repeated reference to FAR 52.227-14 masks the fact that DOE's clause is substantially different.

Copyright ownership is obviously important to colleges and universities. If DOE approval to claim copyright ownership is not granted, the work, by definition, enters the public domain. Since DOE's authorization to use FAR Alternate IV remains unpredictable, university negotiators need to be vigilant to assure that Alternate IV will be used whenever possible. A strong argument could be made that contracts should be governed by the (d)(3) addition to the basic FAR data rights clause only where development and delivery of software is the central purpose of the award, comparable in effect to work-for-hire contracts. All other awards, where software is merely an incidental product, should be governed by Alternate IV.

Without copyright ownership, universities may encounter problems. For example, universities could deliver to the DOE a derivative of copyrighted software or deliver software that has multiple purposes or uses, which require that it be protected and not pass into the public domain. In those cases, the university is obligated to disclose the circumstances to DOE at the contracting stage and to provide the government with the appropriate limited or restricted rights. It is also not unusual for universities to informally share software with each other, as under academic license, and to provide each other the right to use the software in government contracts. When working with the DOE, the university contractor may find that the rights it has obtained from third parties are not sufficient to meet the broad rights upon which DOE may insist. DOE also enforces liability provisions, requiring the contractor to agree it will not knowingly include any material copyrighted by others without appropriate licenses or consent.

National Aeronautics and Space Administration FAR Supplement

NASA rights in data provisions are set forth in the NASA FAR Supplement (NFS) Part 1827.404. NASA generally follows FAR data rights concepts. However, NASA also adds to the general FAR rights in data clause a (d)(3) restriction similar to DOE requiring NASA permission to copyright, publish, or release computer software first produced in the performance of the contract (NFS 1852.227-14). NASA cites as reason its intent is to ensure the most expeditious dissemination of computer software developed by it or its contractor.

Fortunately, the NFS also states that the (d)(3) addition should not be used in contracts for basic or applied research with universities or colleges. It also indicates that FAR Alternate I for delivery of limited rights data may be appropriate for such contracts. The contracting officer may grant permission for the contractor to copyright, publish, or release to others computer software first produced in the performance of a contract. However, certain specified conditions must exist and the concurrence of the NASA Office of Aerospace Technology, Commercial Technology Division (Code RC) must be obtained.

Rights in Data and Computer Software under Grants and Cooperative Agreements

For the most part, federal grant and cooperative agreement regulations and policies on RITD are fairly simple and straightforward when compared to the procurement regula-

tions. In general, grant recipients may copyright any work developed under an award. The federal awarding agency reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use the work for federal purposes, and to authorize others to do so. Absent, for the most part, are the detailed definitions of technical data and provisions regarding rights and deliverables.

Most agency grant regulations require that an awardee institution broadly disseminate the sponsored program's results and materials. This goal fits in well with universities' primary academic purposes. Even so, research administrators need to be familiar with some of the peculiarities in federal agency definitions of data and should remember that some agencies incorporate FAR language into grants or cooperative agreements. In essence, however, all federal agencies must adhere to the intellectual property policy stated in OMB Circular A-110 (Section __36 Intangible Property), which includes data and copyrights.

Section 36 of OMB Circular A-110, Data Rights and FOIA (2 CFR, also available at http://www.whitehouse.gov/omb/circulars/a110/a110.html), gives grant recipients the right to copyright any work developed under the award and provides the government with a license right (__36(a)). OMB Circular A-110 at paragraph 36 states, "A recipient may copyright any work that is subject to copyright and was developed, or for which ownership was purchased, under an award. Actual grant terms and conditions regarding rights in data are governed by the individual policies of the granting agencies. The government has the right to obtain, reproduce, publish, or otherwise use data first produced under an award, and authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes (__36[c]). The circular applies to all federal agency grants to and agreements with institutions of higher education, hospitals, and other nonprofit organizations. Its provisions apply to all agencies unless different provisions are required by statute or approved by OMB."

Section __36(d) of the circular implements the Shelby Amendment (P. L. 105-277) included in OMB's FY99 appropriation. It gives the public the right to request data in published research findings that are used in developing agency regulations. It provides

that, in response to a Freedom of Information Act (FOIA) request for such research data produced under an award and used by the federal government in developing an agency regulation, the federal awarding agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public under FOIA.

While no general definition of data is included in Circular A-110, for purposes of __36(d), research data are defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings. Research data does not include any of the following

- preliminary analyses
- drafts of scientific papers
- plans for future research
- peer reviews
- communications with colleagues
- physical objects, e.g., laboratory samples
- trade secrets
- commercial information
- materials necessarily held confidential until published
- personnel records, medical information, and similar information, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy

Circular A-110 defines "published" and "used by the federal government in developing an agency action that has the force and effect of law." Research data is published when the research findings are published in a peer-reviewed scientific or technical journal or when a federal agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law.

A related statutory provision pertaining to data with implications for universities is the Emerson Amendment to the FY01 Treasury Appropriations Act (P. L. 106-554). Section 515 directed OMB to issue government-wide guidelines that provide policy and procedural guidance to federal agencies for ensuring and maximizing the quality, objectivity, utility,

and integrity of information (including statistical information) disseminated by federal agencies. OMB published final guidelines on February 22, 2002 (67 FR 8452).

Federal Demonstration Partnership

The FDP is a cooperative activity currently involving ten federal agencies and ninety-eight institutional recipients of federal funds. (See http://thefdp.org/.) For those universities participating in FDP, FDP general terms and conditions (http://www.nsf.gov/awards/managing/fed_dem_part.jsp?org=NSF) apply to grant awards from the member federal agencies. FDP general terms and conditions on rights in data essentially follow OMB Circular A-110 __36. They do not waive the federal government's rights to data first produced under the award. Agencies may include additional agency-specific terms and conditions for RITD. However, as noted, there has been a trend toward greater uniformity among the agencies in rights to data under federal grants. This applies particularly to RITD among the participating FDP federal agencies.

National Institutes of Health

The NIH policy, as set forth in the NIH Grant Policy Statement (GPS), provides that in general, grantees own the rights in data resulting from a grant-supported project. (See http://grants1.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm#_Toc54600131.) Special terms and conditions of the award may indicate alternative rights. Except as otherwise provided in the terms and conditions of an award, any publications, data, or other copyrightable works developed under an NIH grant may be copyrighted without NIH approval. Rights in data also extend to students, fellows, or trainees under awards whose primary purpose is educational, with the authors free to copyright works without NIH approval. In all cases, NIH must be given a royalty-free, nonexclusive, and irrevocable license for the federal government to reproduce, publish, or otherwise use the material and to authorize others to do so for federal purposes. Data developed by a consortium participant also is subject to this policy. NIH also participates in FDP, and follows FDP general terms and conditions on RITD with FDP member universities.

Interestingly, NIH GPS includes a definition of data. For NIH purposes, data means recorded information, regardless of the form or media on which it may be recorded, and

includes writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, workflow charts, equipment descriptions, data files, data processing, or computer programs (software), statistical records, and other research data.

As a means of sharing knowledge, NIH encourages grantees to arrange for publication of NIH-supported original research in primary scientific journals. Grantees also should assert copyright in scientific and technical articles based on data produced under the grant where necessary to effect journal publication or inclusion in proceedings associated with professional activities.

NIH endorses the sharing of final research data to expedited translation of research results into knowledge, products, and procedures to improve human health. Its policy encourages the timely release and sharing of final research data from NIH-supported studies for use by other researchers. Timely release and sharing is defined as no later than the acceptance for publication of the main findings from the final data set. Effective with the October 1, 2003, receipt date, investigators submitting an NIH application seeking $500,000 or more in direct costs in any single budget period are expected to include a plan for data sharing or state why data sharing is not possible.

NIH also considers the sharing of unique research resources (also called research tools) an important means to enhance the value of NIH-sponsored research. To provide further clarification of the NIH policy on disseminating unique research resources, NIH published *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources* (64 FR 72090, December 23, 1999), which is available on the NIH Web site at http://ott.od.nih.gov/NewPages/ Rtguide_final.html. These guidelines are incorporated in NIH GPS and should be viewed as a grant condition. On May 7, 2004, NIH published a new policy on sharing and distributing unique model organism research resources generated through the use of NIH funds (available at http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html [NOT-OD-04-042]). NIH characterized this policy as an extension of the research tools policy. It requires that plans for sharing and distributing unique model

organism research resources be included in NIH grant applications or contract proposals beginning with the October 1, 2004, receipt date.

In February 2005, NIH published a policy on enhancing public access to publications resulting from NIH-funded research. Beginning May 2, 2005, NIH-funded investigators are requested to submit to the NIH National Library of Medicine's PubMed Central (PMC) an electronic version of the author's final manuscript upon acceptance for publication. This final NIH public access policy reflects modifications and clarifications to the public access policy initially proposed in September 2004. The most significant change in the policy from that originally proposed is to provide more flexibility for authors to specify the timing of the posting of their final manuscripts for public accessibility through PMC. The proposed policy indicated a six-month delay of posting through PMC. The policy now requests and strongly encourages that authors specify posting of their final manuscripts for public accessibility as soon as possible (and within twelve months of the publisher's official date of final publication). The policy also clarifies that the publication date is the publisher's official date of final publication. Reservation of rights by grantees and/or investigators in assignment agreements with journal publishers may be necessary to comply with the new NIH policy.

National Science Foundation

The NSF policy is to encourage open scientific and engineering communication. The NSF normally allows grantees to retain principal legal rights to intellectual property developed under NSF grants to provide incentives for development and dissemination of inventions, software, and publications that can enhance their usefulness, accessibility, and upkeep. Such incentives do not, however, reduce the responsibility that investigators and organizations have as members of the scientific and engineering community to make results, data, and collections available to other researchers.

NSF states in its *Grant Policy Manual* (Section 732, available at http://www.nsf.gov/publications/pub_summ.jsp?ods_key=gpm) that NSF normally will acquire only such rights to copyrightable material as are needed to achieve its purposes or to comply with the requirements of any applicable government-wide policy or international agreement.

To preserve incentives for private dissemination and development, NSF normally will not restrict, or take any part of income earned from, copyrightable material except as necessary to comply with the requirements of any applicable government-wide policy or international agreement. In exceptional circumstances, NSF may restrict or eliminate a grantee's control of NSF-supported copyrightable material and of income earned from it, if NSF determines that this would best serve the purposes of a particular program or grant.

NSF's standard copyright clause (No. 18 in NSF's "Grant General Conditions") states that, except as otherwise specified in the grant or in the clause, the grantee may own or permit others to own copyright in all subject writings. The grantee agrees that if it or anyone else does own copyright in a subject writing, the federal government will have a nonexclusive, nontransferable, irrevocable, royalty-free license to exercise or have exercised for or on behalf of the U.S. throughout the world all the exclusive rights provided by copyright. Special copyright provisions may be negotiated in specific situations, such as grants affected by international agreements.

NSF has a specific policy on the dissemination and sharing of research results (GPM, Section 734). This policy states that investigators are expected to promptly prepare and submit for publication, with authorship that accurately reflects the contributions of those involved, all significant findings from work conducted under NSF grants. Grantees are expected to permit and encourage such publication by those actually performing that work, unless a grantee intends to publish or disseminate such findings itself. Investigators also are expected to share with other researchers, at no more than incremental cost and within a reasonable time, the primary data, samples, physical collections. and other supporting materials created or gathered in the course of work under NSF grants. Grantees are expected to encourage and facilitate such sharing. Privileged or confidential information should be released only in a form that protects the privacy of individuals and subjects involved. Investigators and grantees are encouraged to share software and inventions created under the grant or otherwise make them or their products widely available and usable.

NSF also participates in FDP and has a similar provision on data sharing and dissemination in its FDP agency-specific requirements (Article 14.a.). It otherwise follows the FDP general terms and conditions with regard to RITD.

Department of Defense

DOD Grant and Agreement Regulations (DODGARS) follow OMB Circular A-110 Section __36 with regard to rights in data (see DODGARS Section 32.36, available at http://www.dtic.mil/whs/directives/corres/html/32106r.htm). The recipient may copyright any work that is subject to copyright and was developed, or for which ownership was purchased, under an award. DOD components reserve a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use the work for federal purposes and to authorize others to do so. The federal government has the right to obtain, reproduce, publish, or otherwise use the data first produced under an award and to authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes. DODGARS also set forth the A-110 __36 (d) Shelby Amendment provisions, and define research data for these purposes (32.36[d][2][I]).

Several DOD research agencies participate in FDP and follow the general FDP terms and conditions for the participating FDP universities. These include the Air Force Office of Scientific Research (AFOSR), Army Medical Research Acquisition Activity (USAMRAA), Army Research Office (ARO), and the Office of Naval Research (ONR). None of these DOD components currently have agency-specific conditions pertaining to rights in data. The general grant terms and conditions of the service agencies also mostly follow OMB Circular A-110. For example, AFOSR provides (http://www.afosr.af.mil/pages/afrtad06.htm) that all rights and title to data and technical data generated under the grant shall vest in the grantee. The grantee grants to the U.S. government a nonexclusive, nontransferable, royalty-free, fully paid-up license to use, duplicate, or disclose for governmental purposes any data and technical data. The grantee reserves the right to protect by copyright original works developed under the grant, and all such copyrights will be in the name of the grantee. The grantee grants to the U.S. government a nonexclusive, nontransferable, royalty-free, fully paid-up license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, for governmental purposes, any copyrighted materials developed under the grant and to authorize others to do so.

However, AFOSR goes on to provide that the grantee is responsible for affixing appropriate markings indicating the rights of the government on all data and technical data delivered under the grant. The government shall be deemed to have unlimited rights in all data and technical data delivered without markings. ARO and ONR reference the DODGARS and OMB Circular A-110 but do not specifically address rights in data in its general grant terms and conditions.

Department of Energy

In 1996, DOE migrated its approach to rights in data under contracts to its approach under grants, despite protests from COGR and universities. DOE has not justified its injection of acquisition terms into assistance awards beyond citing its special mission and its years of unchallenged practice of having done this de facto. When questioned about the rules, DOE explained to COGR its position as follows: "You question our amendment of the assistance regulations in a manner that is consistent with the changes to our procurement regulations. As a preface, the Department of Energy operates in the area of rights in data in a manner that reflects a statutory duty to disseminate the product of our contracts and assistance agreements. This rule follows this Department's long history of linking the treatment of data first produced under contracts with the treatment of data first produced under assistance agreements."

DOE claims it took great care to make sure its language, taken from procurement language, would comply with OMB Circular A-110. In its explanatory letter to COGR, DOE stated: "In writing the final rule, we have considered OMB Circular A-110 and found the copyright license retained by the government to be broader in assistance than in the case of contracts. Paragraph 36 'Intangible Property' of OMB Circular A-110 states that the grant recipient may copyright any work developed under an award. The agency reserves a 'royalty-free, nonexclusive and irrevocable right to reproduce, *publish* (emphasis added), or otherwise use the work for Federal purposes and to authorize others to do so.' The license retained by the government in computer software first produced and copyrighted by the contractor under Alt. IV of FAR 52.227-14 does not include the right to publish as required by OMB Circular A-110. While we were sympathetic with the case you make that assistance should confer a broader set of rights, we were constrained by the Circular. We believe the

right to copyright and the retained government license provided in both OMB Circular A-110 and in our assistance regulations are equivalent."

The DOE Financial Assistance Rules' provisions on patents and data are available at http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2003/10cfr600.27.htm. They incorporate the policies, procedures, and clauses of DEAR. In the intellectual property section, at 10 CFR 600.136, DOE permits institutions of higher education and other nonprofit organizations that receive DOE assistance awards to claim copyright with a license reserved to DOE to use the work for federal purposes, but indicates that, in addition, recipients must follow DEAR requirements. The DOE has the right to obtain, reproduce, publish, or otherwise use the data first produced under an award and authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes. As a result, DOE grant awards are governed by broader patent and data rights provisions than those used by other federal agencies and these DOE requirements are expressed and made enforceable in procurement terms.

For grants as well as for contracts, DOE uses the FAR general data rights clause at 48 CFR 52.227-14. The FAR clause is amended in the definitions section (a) and by inserting (d)(3) of 48 CFR 927-409(a)(1). Use of Alternative V is also mandatory. In addition, solicitations must include the representation of limited rights data and restricted computer software provisions at 48 CFR 52.227-15.

The general instructions to DOE grantees are cited at 10 CFR 600.27(b)(2)(i)(A). Section 27(b)(2) (B) addresses the special provisions for university awardees regarding copyright. Except as otherwise specifically provided in the award, subparagraph (d)(3) of DEARS clause requiring prior permission from DOE before awardees may secure copyright protection, will be deleted and the equivalent of FAR 52.227-14 Alternative IV will be authorized. This means that university grantees may "establish" copyright in all data first produced under the award, including computer software, without having to specifically resort to the "Alternate IV class deviation" for universities under DOE contracts.

With respect to universities' right to establish copyright and the terms of the retained government copyright license, DOE's assistance regulations are compatible with and do not exceed OMB Circular A-110 guidance. However, with respect to other data rights, university grantees have to accept the same expanded DOE rights as in contracts (see "Department of Energy Acquisition Regulations" above). As with contracts, the general data rights provisions for grants also require the use of Alternate V, which gives the government the authority to inspect records. Solicitations must also include the "Representations of Limited Rights Data and Restricted Computer Software" at 48 CFR52.227-15. DOE grants officers will also incorporate "Rights to Proposal Data, (Technical)" (52.227-23) and "Additional Data Requirements" (52.227-16).

For copyright protection for data first produced under an award, DOE regulations are within the parameters of OMB Circular A-110, including the right to publish university-generated software. DOE has expanded its rights in the pre-grant area ("Unlimited Rights in Proposal Data") and in the post-grant area ("Additional Technical Data" clause) compared with the rights retained by other agencies, again citing its special mission under the Atomic Energy Act. In addition, grants officers are instructed to treat data rights matters in accordance with 48 CFR 927.4—the DOE technical data and copyright policy for procurements.

Finally, as a reminder about liability, DOE imposes liabilities on grantees as well as contractors for knowingly including any material copyrighted by others in any written material furnished or delivered under an award, unless the appropriate licenses or approvals have been obtained.

The DOE participates in the FDP. However, its current agency-specific requirements do not address intellectual property rights. Thus, for FDP member institutions, the DOE terms and conditions on copyright and rights in data in grant awards are the general FDP terms and conditions. This creates a substantial dichotomy between FDP and non-FDP institutions with regard to the terms and conditions governing RITD under DOE awards.

Other Agencies

National Aeronautics and Space Administration

NASA follows OMB Circular A-110 with regard to rights in data. According to the *NASA Grants Handbook* (Section 1260.136, available at http://ec.msfc.nasa.gov/hq/grantb.html#1260.136), the recipient may assert copyright in any work that is copyrightable and was created, or for which copyright ownership was purchased, under an award. NASA is granted a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, prepare derivative works, or otherwise use the work for federal purposes and to authorize others to do so. NASA has the right to obtain, reproduce, publish, or otherwise use the data first produced under an award and to authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes.

NASA also is a member of FDP. Its agency-specific requirements do not address copyright or RITD.

Environmental Protection Agency

EPA also follows OMB Circular A-110 with regard to data. The EPA grant regulations (Section 30.36, available at http://www.access.gpo.gov/nara/cfr/waisidx_00/40cfr30_00.html) provide that grant recipients may copyright any work that is subject to copyright and was developed, or for which ownership was purchased, under an award. The EPA reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use the work for federal purposes and to authorize others to do so. The federal government has the right to obtain, reproduce, publish, or otherwise use the data first produced under an award and to authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes.

The EPA also participates in FDP. It has no agency-specific requirements for rights in data or copyright. The agency specifics do require recipients to provide copies of peer-reviewed journal articles to EPA and to follow EPA requirements for acknowledgment of EPA support.

Department of Agriculture

The U.S. Department of Agriculture agency with which universities most frequently deal is the Cooperative State Research, Education, and Extension Service (CSREES). The CSREES award terms and conditions also follow OMB Circular A-110 with regard to rights in data and copyright (7 CFR 3019.36). However, CSREES has a special grant condition that if genome sequence data have been obtained, the sequence must be submitted to GenBank. The date of submission to GenBank must be on the same date as the government's right to publish as indicated in the terms and conditions. Submission of data to GenBank is without charge. Information concerning GenBank protocols may be obtained via http://www.ncbi.nlm.nih.gov/ or by contacting the National Center for Biotechnology Information.

The CSREES also is an FDP member agency. Its agency-specific conditions contain a similar requirement for GenBank submission.

Department of Education

The Department of Education General Administrative Regulations provide guidance for the administration of grants to universities, hospitals, and other nonprofit organizations. The regulations state (Section 74.36, available at http://www.ed.gov/policy/fund/reg/edgarReg/edlite-part74a.html) that universities are free to assert copyright ownership in material developed under the grant. The Department of Education and other agencies receive a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use and to authorize others to use the work for federal government purposes. The Department of Education is not a member of the FDP.

National Endowment of the Arts/National Endowment for the Humanities

The national foundations on the arts and humanities' copyright ownership and rights to the federal government are the same as the other agencies above. Each agency receives a royalty-free, nonexclusive, and irrevocable license to reproduce, publish, and to authorize others to use, for federal government purposes, the copyright in any work developed under a grant, subgrant, or contract. The National Endowment for the Humanities (NEH)

states that "federal purposes" include the use of grant products in activities or programs undertaken by the federal government, in response to a governmental request, or as otherwise required by federal law. However, the federal government's use of copyrighted materials is not intended to interfere with or disadvantage the grantee or assignee in the sale and distribution of the grant product (http://www.neh.gov/manage/gtcao.html#intangible). The National Endowment of the Arts and the NEH do not participate in FDP.

Department of Transportation

The Department of Transportation (DOT) also follows OMB Circular A-110. Its grant regulations (49 CFR Part 19) incorporate Section__36 of Circular A-110 (see Section 19.36 at http://www.dot.gov/ost/m60/grant/49cfr19.htm#19.36). However, DOT regulations include a provision on a property trust relationship (19.37). This provides that all property (including intangible property) and debt instruments that are acquired or improved with federal funds shall be held in trust by the recipient as trustee for the beneficiaries of the project or program under which the property was acquired or improved. DOT may require recipients to record liens or other appropriate notices of record to indicate that personal or real property has been acquired or improved with federal funds and that use and disposition conditions apply to the property. DOT does not participate in FDP.

Protection, Marking, and Management of Data, Noncommercial Technical Data, Noncommercial Software, and Noncommercial Software Documentation

One of the most important responsibilities of an institution with respect to data produced or delivered to the government is to protect the university and government rights appropriately. Federal contract and some grant regulations, especially those of DOD and DOE, rigorously require that technical data or computer software be marked with a proper notice identifying all sections where the government has limited rights. If the restricted data or computer software is not appropriately marked in accordance with the contract regulations, the government by default obtains unlimited rights. Simply stated: proprietary data that are not marked properly are lost.

There are other traps for the unwary. If an institution marks the technical data and computer software, but the marking is done incorrectly, i.e., not in accordance with agency regulations, the government may also obtain unlimited rights. Protection and marking requirements vary among agencies and are different under contracts and grants. The following discussion provides information about some of the intricacies in marking data and software and the consequences of not doing it properly.

FAR Marking Requirements

The FAR clauses state precisely what a limited or restricted rights notice or legend must say when it is placed on data and software. Generally, the statement should provide notice to the government that it may reproduce the data for government purposes only, but that the government may not use it for manufacturing purposes or disclose the data outside the government.

Unlike DFARS, FAR clauses do not state where to place the notice on the data and computer software. For instance, they are silent as to whether each page of the data should be marked as opposed to marking the first page or first screen on the software or marking just the software packaging.

If data (including software) are delivered without either the limited or restricted rights legend or copyright notice where appropriate, FAR presumes that the institution provided the government with unlimited rights.

The government has several options if the data or software are incorrectly marked. The government has the right to ignore the markings, cancel the markings, or to return the data to the contractor as nonacceptable. Alternately, the government may allow the remarking of the data and software at the contractor's expense. When research administrators know that a contract, regulated by FAR clauses, produces deliverable data, it is critically important for them to work with faculty and members of the research program to educate them on the appropriate way to mark their deliverables to the government. This is particularly needed if it is likely that a corporate subcontractor or corporate collaborator will be involved, there are already existing copyrighted data or software that

will be delivered, or there is any opportunity to transfer or commercialize the data or software. Since FAR does not provide as much guidance in marking and protecting data and software, it is recommended that universities incorporate DFARS standards, which are discussed below, into their procedures and policies for protecting data and software.

DFARS Marking Requirements (DFARS 252.227-701[f])

When the DOD revised its rights in technical data and computer software clauses in 1995, it also developed much clearer instructions to contractors for the marking and delivery of data and software to the government. Unfortunately, this precision is a two-edged sword. While DOD regulations provide more information for marking, they also make it mandatory to mark, in a very prescriptive manner, all restricted data and software delivered to the DOD. The primary reason for the greater attention to marking was the new government purpose rights category for data and computer software developed with mixed funding.

In addition to correctly marking the data and software, the contractor must maintain written records sufficient to justify the validity of any restrictive markings on technical data and software delivered to the DOD. While marking data may be part of the corporate environment, it is not part of the daily life of many universities and requires an education process for administrators and faculty. DFARS state that the contractor must have written procedures sufficient to assure that the restrictive markings are used only when authorized. Universities may be well-advised to develop a policy or, at a minimum, a written statement explaining the requirements and processes they employ to mark and protect their technical data and software.

After developing a written policy or statement, the next step is to ensure that, during the negotiation processes, the university identifies, in an attachment to the contract, all technical data and computer software that will be delivered to the government with restrictive rights. If during the progress of the research, additional restrictive technical data or computer software are required to be delivered to the government, the university may negotiate with the government to modify the attachment by providing the government with a special form that identifies the additional restricted technical data and computer software.

Once an institution has determined what restrictive data it will deliver to the government, the marking process begins. DFARS 252.227-7013(f) prescribes that one of four allowed markings or legends must be used on the technical data and software. The four allowed markings each apply to one of the four categories of government rights: government purpose rights, limited rights, special license rights, and copyright notice. The notice or legend must contain the identification of the government appropriate restrictive rights, contract number, contractor's name, contractor's address, expiration date of the restrictive rights, and the definition of the government rights and restrictions.

DFARS provides the specific language (see DFARS 252.227-7014 [f][1], [2][3], [4]) that needs to be included in the restricted rights legend or notice and also states how and where the legend should appear on the technical data or software. Legends or notices on the restricted technical or computer software need to be accurate, conspicuous, and legible. In addition, the legend must be placed on the transmittal document or storage container and on each page of the printed material. The DOD also requires that the delivered restricted data be highlighted, underscored, or identified with marks that separate them from the technical data or software that is being delivered to the government without restrictive rights. Technical data transmitted directly from one computer or computer terminal to another must also contain a notice of restrictive use.

Department of Energy Marking Requirements

The DOE uses FAR clauses for marking restricted data delivered to it by a contractor. The DOE's regulations follow the FAR clauses and require that the restricted data be marked with the legend that notifies the government that it has no rights to commercially disclose the restricted data outside of the government.

Alternate VI of the DOE regulations at 952.227-14 provides the government with the appropriate rights should it, or a third party on its behalf, require license rights to any proprietary contract data. If such rights are needed by the government, the contractor agrees to provide to the government and responsible third parties a nonexclusive license in any limited rights data or restricted computer software on terms and conditions reasonable under the circumstances. There are few circumstances under which the contractor

will not have to provide the government with a nonexclusive license. The most common circumstances are: (1) the contractor can demonstrate to the satisfaction of DOE that the data are not essential to the design and fabrication of the processes developed under the contract, (2) such data have a commercially competitive alternative, (3) the contractor has already supplied the data in sufficient quantity to the government, or (4) the data can be obtained from another firm skilled in the art of manufacturing items.

Universities may not need the benefit of these rights in data clauses as independent contractors. However, when they subcontract or do collaborative work with industry, proper use of these clauses will be very important to industrial partners.

Marking Requirements for Grants

Generally, grants do not have requirements for the marking and protection of data and software created or delivered under a grant project. In fact, as stated earlier, the primary goal of the granting agencies is to disseminate the research results. However, institutions and faculty do have to take affirmative steps in identifying data and software that were created under the sponsored program, and they must correctly mark restricted rights data that are delivered to the government.

NSF guidelines illustrate basic grant requirements for marking publications that are based on or developed under federal financial support. All such publications are required to include an acknowledgment of the financial assistance. The required acknowledgment states: "This material is based on work supported by the National Science Foundation under Grant No.___." Disclaimers are also required on all publications that are not published as scientific articles or papers appearing in scientific, technical, or professional journals. The disclaimer should read: "Any opinions, findings and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect those of the National Science Foundation."

Most grant guidelines are silent on how to mark restrictive data delivered to the government. However, most grant guidelines clearly state that if unmarked data or software are delivered to the government without restrictive markings, the government obtains an

unlimited license for any use in the delivered data. By using DFARS marking requirements, an institution will be assured of correctly marking and retaining its own or its subcontractor's rights to the delivered restrictive data.

Conclusion

Users are cautioned that the federal policies and regulations cited in this chapter are subject to change. When dealing with specific issues and requirements, users should consult the original source material. Also, as discussed above, the treatment of rights in data in the federal regulations, particularly with regard to copyright and computer software, does not necessarily reflect the current status of the law in these areas. For this reason, additional changes may be expected in the near future, particularly given the pending revision of FAR Part 27.

Notes

1. See Diane Sidebottom, "Intellectual Property in Federal Government Contracts: The Past, The Present, and One Possible Future;" *Public Contract Law Journal 33*, no.1 (2003).
2. A proposed "plain language" rewrite of FAR Part 27, "Patents, Data, and Copyrights" was announced in the *Federal Register* on May 28, 2003 (68 FR 31790). The rewrite contained few substantive policy changes of importance for universities. However, a number of computer and software companies and associations expressed concerns about some of the provisions regarding the definition of and rights to commercial software. A final version was still pending as of August 2005.
3. As a matter of law, copyright attaches upon creation of the work, so this clause more accurately should require approval of the contracting officer to perfect the copyright. See Sidebottom, supra note 1.
4. 10 USC 2320 (P.L. 98-525 1984). The statute has been amended several times. A DOD-Industry Advisory Committee on Rights in Technical Data also was established by statute.
5. Because much computer software has been patentable since the 1998 Federal Circuit Court of Appeals decision, *State Street Bank v. Signature Financial Group* 149 F.3d 1368 (Fed. Cir. 1998), one would expect that patent rights in soft-

ware are commonly considered as subject to the Bayh-Dole Act, although agencies apparently continue to apply FAR, DFARS, and agency-specific data rights clauses which grant very different rights than Bayh-Dole. The pending revision of FAR Part 27 hopefully will address this dichotomy.

6. See *The Boeing Company v. Sierracin Corp.,* 738 P.2d 665, 676, 4 U.S.P.Q.2d (BNA) 1417 (1987), wherein the court held that the mandatory submission of trade secret data to the Federal Aviation Administration did not destroy the confidentiality of the trade secrets.

State Sovereign Immunity and Technology Transfer

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In June 1999, the United States Supreme Court issued two decisions recognizing that states have sovereign immunity from suits for intellectual property infringement. These two decisions, *Florida Prepaid*[1] and *College Savings Bank*,[2] prompted several bills in Congress aimed at establishing state intellectual property liability.[3] The bills, versions of the Intellectual Property Restoration Act, would require states to waive their immunity as a precondition to being able to fully enforce their own intellectual property rights. If enacted, this legislation will have a significant impact on technology transfer. The purpose of this article is to explain the historical and legal context for the Supreme Court's decisions and the Intellectual Property Restoration Act.

Part I: The Meaning of the Eleventh Amendment

The Constitutional Debates

To understand the current issues regarding sovereign immunity, it is helpful to trace their historical roots in the debates leading to ratification of the U.S. Constitution. During those debates, the extent to which the Constitution would require the states to relinquish power to the new national government was a subject of impassioned argument. One such argument—the one most relevant here—focused on whether the Constitution would allow a state to be sued in federal court without the state's consent.[4] The states conceived of themselves as sovereign entities, and, according to the traditional, monarchy-based jurisprudence, immunity from suit was a necessary attribute of sovereignty.[5]
The ratification debates specifically focused on two provisions in Article III, Section 2 of the Constitution, which address suits in federal court against state governments.[6] These provisions provide that the judicial power of the United States extends to suits "between a State and Citizens of another state" and "between a State . . . and foreign states, citizens or subjects." Two opposing views emerged as to the meaning of these provisions.

One view, held most notably by Alexander Hamilton and James Madison, was that these provisions did not override state sovereignty.[7] According to Hamilton and Madison, the provisions were permissive only: they gave the federal court jurisdiction over a suit against a state only if the state consented. The second view was that the plain language of Article III gave federal courts jurisdiction whether or not the state consented. This view also had distinguished adherents, such as Patrick Henry and George Mason.[8] As a matter of historical interpretation, which of these two views prevailed at the time of the Constitution's ratification is subject to debate.[9] However, as will be explained below, the Supreme Court has sided with the view that federal court jurisdiction requires state consent, and, accordingly, that the states entered the union retaining this important aspect of sovereignty.

Chisholm v. Georgia and Passage of the Eleventh Amendment

Notwithstanding the debate and disagreement over state sovereignty, the Constitution was ratified containing the provisions of Article III, Section 2. The Supreme Court's first occasion to interpret those provisions came in 1794 in *Chisholm v. Georgia*.[10] The Eleventh Amendment was adopted in direct response to the Court's decision in *Chisholm*. The case arose from a dispute between the State of Georgia and a citizen of South Carolina, Robert Farquhar, who had supplied materials to Georgia during the Revolutionary War. Georgia did not pay Farquhar for the materials. Farquhar died, and Alexander Chisholm, his executor, sued the State of Georgia on the debt. The case was filed directly in the Supreme Court under a provision in the Judiciary Act of 1789 giving the Supreme Court original jurisdiction over controversies between states and citizens of another state.[11] Georgia did not appear for the hearing, but filed a protest, in which it contested the Court's jurisdiction.

In a four-to-one decision (the Court at that time having only five justices), four justices ruled in favor of Chisholm and one for Georgia. The majority accepted the view that Article III allowed an unconsenting state to be sued in federal court by a citizen of another state. In so holding, the Court sided with the view that the plain language of Article III, Section 2 gave federal courts jurisdiction over suits between a state and citizens of another state regardless of whether the state consented to the suit.

The states were outraged by *Chisholm,* and Congress took quick action. Within a week of the Court's decision, the text of what would become the Eleventh Amendment had been introduced in Congress.[12] A year later, Congress approved the Eleventh Amendment and submitted it for ratification by the states. President Adams declared the ratification process complete in 1798.[13] As ratified, the Eleventh Amendment provides: "The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by citizens of another state, or by citizens or subjects of any foreign state."

Hans v. Louisiana

The language of the Eleventh Amendment corresponds to the language in Article III, Section 2 that was the subject of debate during the state ratification conventions, and it was specifically tailored to the situation in *Chisholm*—a citizen of South Carolina suing the State of Georgia. That is, whereas the text of Article III, Section 2 provides that the judicial power of the United States extends to suits "between a state and Citizens of another state," the Eleventh Amendment says, in effect, "No, it does not." This parallelism supports viewing the Eleventh Amendment narrowly as simply limiting federal jurisdiction when it is based solely on the identity of the parties to the suit—so-called diversity jurisdiction.

In other words, one might suppose that, if a citizen of one state wanted to sue another state in federal court, the citizen could not, because of the Eleventh Amendment, rely merely on the language in Article III, Section 2 to obtain federal court jurisdiction. However, if the citizen had some other basis on which to claim federal jurisdiction, then, on this interpretation, the Eleventh Amendment would not preclude jurisdiction. In particular, on this "diversity interpretation," federal jurisdiction based not on diversity but on the subject matter of the suit—federal question jurisdiction—was not affected by the Eleventh Amendment.

Whatever the merits of the diversity interpretation, the Supreme Court decisively rejected it in 1890 in *Hans v. Louisiana*.[14] In *Hans,* the only issue before the Court was whether a state could be sued in federal court by one of its own citizens "upon a sugges-

tion that the case is one that arises under the constitution or laws of the United States," in other words, on the basis of federal question jurisdiction.[15] The Court held that the Eleventh Amendment barred the suit. According to the Court, the Eleventh Amendment had merely corrected the error of *Chisholm* and reestablished the correct understanding that the Constitution embodied the "established principle of jurisprudence in all civilized nations that the sovereign cannot be sued in its own courts, or in any other, without its consent and permission."[16]

Alden v. Maine

As recently as 1999, the Court reaffirmed the broad nature of sovereign immunity reestablished by the Eleventh Amendment. In *Alden v. Maine*, the Court held that the State of Maine could not be sued in its own courts without its consent by state employees alleging violations of the federal Fair Labor Standards Act.[17] As in *Hans* where the literal language of the Eleventh Amendment did not address suits by a state's own citizens, in *Alden*, the literal language of the Eleventh Amendment did not address suits in a state's own courts. Following the same theory of sovereign immunity it had declared in *Hans*, the Court explained that "sovereign immunity derives not from the Eleventh Amendment but from the structure of the original constitution itself."[18]

According to the Court, that structure of the original constitution defined a federal system that preserved state sovereignty in two ways. First, it reserves to the states "a substantial portion of the Nation's primary sovereignty, together with the dignity and essential attributes inhering in that status."[19] The Court explained that the states are supreme within their own spheres, no more subject to the federal government in their respective spheres than the federal government is subject to the states in its sphere.[20] Second, the federal system embraced by the Constitution is not one in which the federal government acts "upon and through the states."[21] Instead, it is a system in which "the State and Federal Governments would exercise concurrent authority over the people."[22]

Part II: Exceptions, Waivers, and Congressional Abrogation

As *Alden* reaffirmed, the federal system created by the Constitution is a balance between state and federal power. That balance gives rise to a number of questions: What exceptions

exist to state sovereign immunity? What constitutes a valid waiver by the state of its sovereign immunity? Under what circumstances may Congress abrogate the states' immunity?

Exceptions to the Immunity

The most important exception to state Eleventh Amendment immunity—and one the Intellectual Property Restoration Act would codify—was announced by the Court in its 1908 decision *Ex Parte Young*.[23] Minnesota had adopted a law limiting railroad rates. Railroad shareholders, believing the law unconstitutional, filed a suit in federal court seeking an injunction against Edward T. Young, the attorney general of Minnesota, to prevent him from enforcing the law. The court issued a preliminary injunction against Young, but he ignored the injunction and began an action against the railroads. Young was cited for contempt and informed that he would be held in custody until he dismissed the action. He then petitioned for habeas corpus to the United States Supreme Court, arguing the injunction was invalid under the Eleventh Amendment. The Court disagreed. The Court's rationale rested on the Supremacy Clause of the Constitution, which says that the Constitution and the laws of the United States are the "supreme Law of the Land."[24] A state cannot violate the Constitution or a law of the United States, and neither can it confer on an individual the authority to do so. Therefore, the Court explained, when a state official acts in violation of the Constitution he "is stripped of his official or representative character and is subjected in his person to the consequences of his individual conduct. The state has no power to impart to him any immunity from responsibility to the supreme authority of the United States."[25]

Ex Parte Young established that the Eleventh Amendment does not bar a suit brought to enjoin a state official from violating the Constitution or the laws of the United States. This exception applies only to injunctions. Suits for money damages against the state remain barred.

Other exceptions to the Eleventh Amendment bar also exist and warrant brief mention. For example, the Eleventh Amendment does not bar suits against public officials in their "individual capacities" as opposed to their "official capacities."[26] The Eleventh Amendment does not bar suits against states in federal court by the federal government[27]

or by sister states.[28] Nor is the Eleventh Amendment a bar to suits against municipalities or political subdivisions of a state,[29] although it may prevent the suit when there is so much state involvement that the judgment would run against the state.[30] Suits against state-related entities such as boards and commissions are also sometimes allowed, depending on whether the court views the entity as really part of the state.[31] Notably, although the law in this area is unsettled, the courts usually view state universities as qualifying for Eleventh Amendment immunity.[32]

State Waivers

A state may waive its Eleventh Amendment immunity. Two types of state waivers are possible. One is where the state expressly agrees to be sued in federal court. Such waivers must include explicitly that the state is willing to be sued in federal court. Thus the Court has held that a valid waiver requires more than just a state's consent to be sued in its own courts[33] and more than a general consent to be sued "in any court of competent jurisdiction."[34] The Court has explained that "although a State's general waiver of sovereign immunity may subject it to suit in state court, it is not enough to waive the immunity guaranteed by the Eleventh Amendment."[35] This is because "the Eleventh Amendment implicates the fundamental constitutional balance between the Federal Government and the States."[36]

The other type of waiver is when the state has not expressly consented to suit in federal court, but its actions imply consent—so-called constructive waivers. The Court has changed its position in this area. In 1964, in *Pardon v. Terminal Railway of Alabama State Docks Department*, the Court held that implied waivers are valid.[37] The State of Alabama was sued for alleged violations of the Federal Employers' Liability Act in the operation of a state railroad. The Court held the state's operation of the state railroad to be an implied consent to suit in federal court under the act.[38]

However, nine years later, in *Employees of the Department of Public Health & Welfare v. Department of Public Health & Welfare*, the Court began to retreat from constructive waivers, holding that a waiver could not be implied absent a clear declaration from Congress that it intended to make states liable if they violated the federal law.[39] Another

year after that, in *Edelman v. Jordan*, the Court refused to infer waiver from the state's participation in a program through which the federal government provided assistance for the operation by the state of a system of public aid.[40] In 1987, in *Welch v. Texas Department of Highways & Public Transportation*, the Court distanced itself still further, overruling Pardon "to the extent [it] is inconsistent with the requirement that an abrogation of Eleventh Amendment immunity by Congress must be expressed in unmistakably clear language."[41] The Court finally overruled *Parden* in *College Savings Bank v. Florida Prepaid Postsecondary Education Expense Board*.[42] Referring to *Parden* as "an elliptical opinion that stands at the nadir of our waiver (and, for that matter, sovereign immunity) jurisprudence,"[43] the Court declared: "*Parden* stands as an anomaly in the jurisprudence of sovereign immunity, and indeed in the jurisprudence of constitutional law. Today, we drop the other shoe: Whatever may remain of our decision in *Parden* is expressly overruled."[44]

In short, state waivers must be explicit and will not be implied from state actions, such as participation in a federally regulated system.

Abrogation by Congress

Congress may abrogate the states' sovereign immunity. Congress' power to do so, however, has been significantly curtailed by the Supreme Court's recent decision.

Fitzpatrick v. Bitzer

The Fourteenth Amendment of the Constitution provides, inter alia, that no state shall "deprive any person of life, liberty, or property without due process of law." Section 5 of the Fourteenth Amendment gives Congress the authority to pass laws to enforce the other provisions of the amendment. In *Fitzpatrick v. Bitzer*,[45] the Court recognized that Section 5 gives Congress the power to abrogate state sovereign immunity.

In *Fitzpatrick*, state employees sued the State of Connecticut for alleged discrimination in the state's retirement benefits plan, in violation of Title VII of the Civil Rights Act of 1964. The lower court ruled that the Eleventh Amendment applied, granted an injunction to prevent ongoing violations, but denied any award of monetary damages against the

state.[46] The issue before the Supreme Court was whether the Eleventh Amendment barred the award of damages. The Court held it did not, because Congress, acting pursuant to its powers under Section 5 of the Fourteenth Amendment, had properly abrogated state immunity from suits under Title VII. The Court explained that the prohibitions of the Fourteenth Amendment are explicitly directed at the states, and Congress is expressly given the authority to enforce those provisions. Accordingly, the Court reasoned that the Fourteenth Amendment, which was passed soon after the Civil War, was a limitation of the power of the states and an enlargement of the power of the federal government.[47] In other words, under the authority of Section 5 of the Fourteenth Amendment, Congress may abrogate state sovereign immunity.

Pennsylvania v. Union Gas

Fitzpatrick left unresolved whether Congress had other authority under the Constitution to abrogate immunity in addition to that provided by the Fourteenth Amendment. The Court addressed that question in 1989 in *Pennsylvania v. Union Gas Co*.[48] The case arose after Pennsylvania and the federal government began environmental cleanup, as required by the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), of coal tar seeping into a creek. To recover some of the cleanup costs, the federal government sued Union Gas Co., whose predecessor had operated on the location and allegedly deposited the coal tar. In response, *Union Gas* filed a third-party action in federal court against Pennsylvania, arguing that the state was liable for a portion of the cleanup cost.

Just four years earlier, in *Atascadero State Hospital v. Scanlon,* the Court had held that when Congress abrogates state sovereign immunity, it must make its intention to do so "unmistakably clear."[49] Accordingly, the first question the Court addressed in Union Gas was whether Congress had made unmistakably clear its intention to subject states to liability under CERCLA. The Court concluded that Congress had done so.[50]

Consequently, the Court next considered whether Congress had abrogated state immunity pursuant to a proper exercise of authority. In enacting CERCLA, Congress had acted pursuant to its powers under the Constitution's Commerce Clause.[51] Therefore, the ques-

tion before the Court in *Union Gas* was whether Congress had the authority under the Commerce Clause to abrogate Eleventh Amendment immunity. The Court held that it did, reasoning that Congress' commerce power inherently carried with it a limitation on state sovereignty.[52]

Copyright Remedy Clarification Act, Trademark Remedy Clarification Act, and Patent Remedy Clarification Act

The combination of *Atascadero* and *Union Gas* indicated that Congress could abrogate Eleventh Amendment immunity pursuant to Congress' Commerce Clause powers if it did so by making its intent "unmistakably clear" in the statute. From the vantage point of 1989, therefore, these decisions presented both a problem to Congress and a solution about how to solve that problem. The problem was that the "unmistakably clear" standard of *Atascadero* threw into question any federal statute purporting to subject states to liability but using language that was anything less than unmistakably clear.

The solution was given by the Court's holding that Congress could abrogate immunity under its Commerce Clause powers. Because so much Congressional legislation falls under the Commerce power, Congress could simply go back to those statutes enacted under its Commerce power and add language to satisfy the unmistakably clear standard. That is what Congress did in 1990 when it enacted the Copyright Remedy Clarification Act (CRCA),[53] and, again in 1992, when it enacted the Trademark Remedy Clarification Act (TRCA)[54] and the Patent Remedy Clarification Act (PRCA).[55] Prior to these acts, in other words, federal copyright, trademark, and patent law arguably failed to make it "unmistakably clear" that Congress intended states to be liable for violations of the federal statutes. The three clarification acts corrected this. Each act was presented as an exercise of Congress' Commerce power—pursuant to *Union Gas*—and, in each case, the amendment was to add language to the federal law stating explicitly that states were subject to liability under the statute.[56]

Seminole Tribe v. Florida

In 1996, only a few years after enactment of the clarification acts, the Court, in an about-face, overruled *Union Gas* and held that Congress may abrogate state sovereign immunity

only under Section 5 of the Fourteenth Amendment. This came in *Seminole Tribe of Florida v. Florida*,[57] a case arising under the Indian Gaming Regulatory Act (IGRA).[58] IGRA, which was passed pursuant to Congress' power under the Indian Commerce Clause,[59] requires states to negotiate with Indian tribes to form compacts to allow gambling on Native American land.[60] IGRA also authorizes a tribe to bring suit in federal court against a state to compel performance of this duty to negotiate.[61]

The Seminole Tribe of Florida sued the State of Florida under IGRA, alleging that Florida had failed to fulfill its obligation to negotiate. Florida asserted the suit was barred by the Eleventh Amendment. The Court agreed, holding that Congress lacks the authority to abrogate immunity under the Indian Commerce Clause or the Interstate Commerce Clause—explicitly overruling *Union Gas*—and that, therefore, IGRA was unconstitutional.[62]

City of Boerne v. Flores

The implications of *Seminole* were profound. Under *Seminole,* the only authority Congress has to abrogate state sovereign immunity is Section 5 of the Fourteenth Amendment. This forces the question as to exactly what constitutes valid Section 5 legislation. The Court addressed that question one year after *Seminole*, in *City of Boerne v. Flores.*[63] There, the City of Boerne, Texas, classified a church building as a historic landmark. The effect of this classification was that the church was prevented from constructing a new facility on its property. The church sued the city under the recently enacted Religious Freedom Restoration Act of 1993 (RFRA). RFRA had been passed in response to the Court's 1990 decision *Employment Div., Dept. of Human Resources of Oregon v. Smith*, in which the Court upheld an Oregon drug law that applied generally but had the incidental effect of preventing members of a Native American church from ingesting peyote for sacramental purposes. The *Smith* Court held the law was not a violation of the Constitution's protection of the free exercise of religion.[64] Congress' stated purpose in enacting RFRA was to overturn *Smith* and reestablish the test used prior to *Smith*. Most importantly, Congress had relied on its Fourteenth Amendment powers in enacting RFRA.[65]

Nonetheless, the Court held that RFRA was unconstitutional because Congress, although it had relied on Section 5 of the Fourteenth Amendment, had not properly exercised its Section 5 authority. The Court explained that Section 5 gives Congress the power "to enforce" the other provisions of the amendment.[66] This enforcement power, the Court explained, does not consist of interpreting the Constitution, but is a matter of remedying or preventing constitutional violations.[67] Invoking *Marbury v. Madison*[68]—the landmark 1803 decision establishing that the Supreme Court as the ultimate authority on what the Constitution means—the Court emphasized that what constitutes a constitutional violation is for the Supreme Court to decide, not Congress.[69] The Court further explained that a valid exercise of Congress' Section 5 enforcement power must be narrowly tailored and a "proportionate" and "congruent" response to prevent and remedy constitutional violations.[70]

Florida Prepaid and College Savings Bank

Two years after *City of Boerne*, the Court announced *Florida Prepaid* and *College Savings Bank*. As shocking as these decisions were to the intellectual property community, they were predictable applications of the Court's Eleventh Amendment jurisprudence. In particular, and with the benefit of hindsight, the two decisions were predictable implications of *Seminole Tribe* and *City of Boerne*. Viewed broadly, and in the larger context of the Court's interpretation of the Eleventh Amendment, both cases are merely instances of the Court's willingness to protect state sovereignty by finding that Congress exceeded its constitutional powers.

In the mid-1990s, College Savings Bank, a New Jersey chartered bank, filed patent and trademark infringement claims against the State of Florida.[71] The suit centered on College Savings' college prepayment program, which consisted of a certificate of deposit, the CollegeSure CD, indexed to college costs and guaranteed to meet future tuition, room, and board. The State of Florida also offered a college prepayment program, through a legislatively created arm, the Florida Prepaid Postsecondary Education Expense Board. The suit alleged that the board, that is, the State of Florida, was infringing College Savings' patent on the method of administering the CollegeSure CD, and that the board had engaged in unfair competition, in violation of the Lanham Act, by making false statements about the board's own prepayment program in its advertising.

The board moved to dismiss both claims on the grounds of the Eleventh Amendment. The district court granted the motion to dismiss the Lanham Act claim, but denied the motion to dismiss the patent-infringement claim.[72] On appeal, the action split in two, the patent-infringement claim going before the Federal Circuit Court of Appeals, and the Lanham Act claim before the Third Circuit Court of Appeals. Both courts of appeal affirmed,[73] and so the dispute arrived in the Supreme Court bifurcated into the patent case appealed from the federal circuit and the Lanham Act case from the third circuit. The Supreme Court accordingly issued two opinions addressing in each the state's Eleventh Amendment defense.

In the patent case, *Florida Prepaid Postsecondary Expense Savings Board v. College Savings Bank*,[74] the Court held that PRCA exceeded the scope of Congress' Section 5 enforcement powers. The problem with PRCA, in the Court's view, was that the law was not "proportionate" and "congruent" because of the absence of any record of a pattern of patent infringements by state governments.[75] In the Lanham Act case, *College Savings Bank v. Florida Postsecondary Expense Savings Board,*[76] the Court held that the right College Savings Bank alleged the state had violated—the right to be free from misrepresentation—was not a property right, hence not a right secured by the Fourteenth Amendment, and, therefore, not a right Congress could legislate to protect under its Section 5 enforcement powers.[77]

The Court did not, in *College Savings Bank,* directly hold that states have sovereign immunity against claims of trademark infringement; likewise, the Court has not explicitly held that states are immune from claims of copyright infringement. Nonetheless, the combination of *Florida Prepaid* and *College Savings Bank* with the Court's other Eleventh Amendment decisions, especially *Seminole Tribe,* leaves little doubt that both TRCA and CRCA are unconstitutional. The attorney general of the United States has informed Congress that TRCA and CRCA probably fail because the legislative record fails to meet the court's requirements for valid Section 5 legislation.[78] Among the courts of appeal, the fifth circuit has held that the University of Houston, an arm of the State of Texas, is immune from copyright infringement suits.[79] In July of 2000, the register of copyrights told Congress that "the CRCA is most likely now bad law."[80]

In sum, the effect of *Florida Prepaid* and *College Savings* is that states have Eleventh Amendment immunity against patent, copyright, and trademark infringement claims. The immunity is subject to exceptions such as *Ex Parte Young* and to Congress' abrogation power under Section 5 of the Fourteenth Amendment.

Later Decisions

After *Florida Prepaid* and *College Savings*, the Court continued to announce other significant Eleventh Amendment decisions that have further drawn out the implications of *Seminole*. These cases bear a brief note here only to illustrate how *Florida Prepaid* and *College Savings* are instances of a broad pattern in the Supreme Court's Eleventh Amendment jurisprudence.

For example, in *Kimel v. Florida Board of Regents*, the Court held that, although Congress had clearly expressed its intent to subject states to suits under the Age Discrimination in Employment Act, the purported abrogation of state sovereign immunity was invalid because Congress exceeded its powers under Section 5.[81] The Court reached a similar result in *Board of Trustees of the University of Alabama v. Garrett* with regard to Title I of the Americans with Disabilities Act, which bars employment discrimination against the disabled.[82] The Court held again that Congress had made its intention to abrogate immunity unmistakably clear, but that Congress had exceeded its Section 5 authority because there was no pattern of state violations against persons with disabilities. In *Federal Maritime Commission v. South Carolina State Ports Authority,* the Court broadened its conception of state sovereign immunity still further in holding that a complaint filed with the Federal Maritime Commission—an administrative tribunal, not a federal court—by a cruise-ship company against the South Carolina Ports Authority was barred by the Eleventh Amendment.[83]

It is possible that the Court has reached its high-water mark in upholding state sovereign immunity. In 2003, the Court held in *Nevada Department of Human Resources v. Hibbs* that Congress acted within its authority under Section 5 when it subjected states to liability for money damages under the Family Medical Leave Act.[84] Similarly, in *Tennessee v. Lane*, the Court held that Title II of the Americans with Disabilities Act, as

it applies to the class of cases implicating the fundamental right of access to the courts, is valid Section 5 legislation.

Part III: Congress' Response, Early Proposals, Their Rationale, and Alternatives

Florida Prepaid and *College Savings* were decided on June 23, 1999. Between 1999 and 2003, during the 106th, 107th, and 108th Congresses, six bills were introduced that aimed to reestablish state liability for infringement, the most recent being S. 1191 and H.R. 2344 in the 108th Congress (2003-04 session).[86] As of the time of this writing, no comparable bills have yet been introduced in the 109th Congressional session (2005-06). Four of the six previous bills, including S. 1191, were introduced by Sen. Patrick Leahy of Vermont. In remarks on the floor of the Senate when he introduced S. 1191, Sen. Leahy explained there was an "urgent need for Congress to respond to the *Florida Prepaid* decisions."[87] He gave two reasons for this urgent need. First, "if we truly believe in fairness, we cannot tolerate a situation in which some participants in the intellectual property system get legal protection but need not adhere to the law themselves."[88] Quoting his colleague Sen. Arlen Specter of Pennsylvania, Leahy said that the *Florida Prepaid* decisions "leave us with an absurd and untenable state of affairs," where "states will enjoy an enormous advantage over their private sector competitors."[89]

Second, Leahy said Congress needed to respond to the *Florida Prepaid* decisions because "they raise broader concerns about the roles of Congress and the Court."[90] In Leahy's view, the Court was "whittling away at the legitimate constitutional authority of the federal government," and Congress should respond "by reinserting our democratic policy choices in legislation that is crafted to meet the Court's stated objections."[91] Implicit in this second reason were both the struggle for power between Congress and the Court, and the balance of power between the federal government and the states. The proposed legislation would have responded to this need by requiring states to waive their sovereign immunity as a condition of full participation in the federal intellectual property system. This is one of several possible approaches.

Notably, one approach Congress has not attempted is to use its enforcement powers under Section 5 of the Fourteenth Amendment and abrogate state sovereign immunity from intellectual property infringement claims. This may be due in part to a September 2001 Government Accounting Office (GAO) report on state sovereign immunity in infringement actions, which had been requested by Sen. Orin Hatch of Utah.[92] The GAO report found that "few accusations of intellectual property infringement appear to have been made against the States either through the courts or administratively."[93] In *Seminole* and its progeny, the Supreme Court had limited Congress' ability to abrogate state sovereign immunity to Congress' enforcement powers under Section 5 of the Fourteenth Amendment and had interpreted those enforcement powers to be properly directly only at patterns of state violations. By failing to find any pattern of state infringement, the GAO report undercut the foundation Congress needed to exercise its Section 5 powers.

Other responses to *Florida Prepaid* and *College Savings* that Congress has considered but not pursued include: (1) amending the federal intellectual property laws to give state courts jurisdiction to hear federal intellectual property claims where a state is charged with infringement, (2) conditioning the states' receipt of certain federal funds on a waiver of immunity from infringement suits, and (3) empowering a federal agency to bring actions against states for violating the intellectual property rights of private parties.[94]

S. 1191 and H.R. 2344

The approach embodied in S. 1191 and H.R. 2344, the Intellectual Property Restoration Act of 2003, would have allowed states to obtain patents and copyright and trademark registrations, but would have limited their enforceability.[95] In particular, the act would have required states to waive their immunity as a precondition of being able to obtain money damages for infringement of intellectual property.[96] If a state did not waive, then the prohibition against damage awards would have applied to any patent, copyright, or federal trademark issued, created, or registered on or after January 1, 2004.[97] The act would thus have affected only such "postcritical date intellectual property;" it would not have affected preexisting patents, copyrights, and trademarks. Nor would it have prevented a state that had not waived from obtaining an injunction to stop infringement. The

act would have applied only to a state's ability to obtain money damage awards. At the same time as the act thus would have weakened a state's offensive position, the act would have also weakened the state's defensive position as regards infringement. It did this in two ways: it would have codified *Ex Parte Young* by providing that state officials could be enjoined from infringing intellectual property and it would have made states liable for takings or due-process violations under the Fifth and Fourteenth Amendments.[98]

The states were given until January 1, 2006, to make a waiver. If a state filed an infringement suit before January 1, 2006, the court was authorized to stay the action to afford the state time to waive its immunity.[99] After that date, a state would not have been able to collect money damages for any infringement of postcritical-date intellectual property that occurred prior to the state waiving its immunity. If a state never waived its immunity, it would not have been able to collect money damages for any infringement of postcritical date intellectual property.

The act's reach was broad. An intellectual property right would have been affected by the act if the state was at any time the legal or beneficial owner of the right.[100] Therefore, a state could not have avoided the effect of the act by, for example, assigning its intellectual properties to a private nonprofit foundation. Licensing of intellectual property by states would also have been affected. Because the state would still be the owner of the licensed intellectual property, the rights could not have been enforced in damages suits by either the state or its licensee. Further, the bill did not allow a state to waive its immunity only in part; waivers were required to be for the state as a whole.[101]

Therefore, for example, a state could not have waived immunity for its universities but preserved immunity for other state agencies. Similarly, a state was required to waive its immunity with respect to all intellectual property to obtain money damage awards with respect to any intellectual property.[102] A state could not have waived its immunity to patent infringement, for example, but retained its immunity to copyright and trademark infringement.

Is the Act Constitutional?

The absence of any version of the Intellectual Property Restoration Act in the 109th Congress suggests that the furor triggered by *Florida Prepaid* and *College Savings* has subsided. If a version of the act were enacted, however, it would likely be challenged on constitutional grounds.

The most likely constitutional challenge is that the act remains an improper attempt by Congress to use its Article I powers (that is, those powers conferred on Congress by Article I of the Constitution) to abrogate state immunity.[103] Such an argument rests on the premise that the act, although purporting to make waivers voluntary, is, in fact, coercive. It threatens to deny states their intellectual property rights unless they waive their immunity.

Such an argument would face significant obstacles. The Court has held that Congress may use its Article I powers to do indirectly what it cannot do directly. For example, in *South Dakota v. Dole*, the Court held that Congress could condition a state's receipt of federal highway funds on the state legislature raising the drinking age to 21.[104] Similarly, in *Petty v. Tennessee-Missouri Bridge Commission*, the Court held that a bistate commission created pursuant to an interstate compact had consented to suit by reason of a suability provision attached to the Congressional approval of the compact.[105] Other decisions by the Court support the general proposition that Congress may hold out *incentives* to influence a state's policy choices.[106] Viewed from this perspective, the act would simply be an attempt to influence states into waiving their immunity by offering the incentive of the privilege to participate fully in the federal intellectual property system.

At the same time, the argument against the act finds support in the Court's clear statements that, in the Eleventh Amendment context, a state's waiver must be fully voluntary to be effective. The *voluntariness* of a state's waiver in response to the act would be highly questionable, because the act threatens states with the loss of their intellectual property rights.

College Savings is instructive on this point and contains language that must give pause to the act's supporters. There, College Savings Bank, relying on the constructive-waiver theory of *Parden*, argued that TRCA clearly put states on notice that they would be subject to suit if they engaged in activities regulated under the Lanham Act. By "engaging in the voluntary and nonessential activity of selling and advertising a for-profit educational investment vehicle in interstate commerce," College Savings Bank argued, the Florida Prepaid Postsecondary Education Board constructively waived its immunity from suit.[107] The Court responded, of course, by overruling *Parden* and the constructive-waiver theory. However, in its discussion, the Court considered an argument in defense of constructive waivers, and the Court's treatment of that argument is suggestive as regard to whether the Court would view the act as unconstitutionally coercive.

The argument was that *Petty* and *Dole* established that Congress may, in the exercise of its Article I powers, extract "constructive waivers" of state sovereign immunity.[108] Distinguishing *Petty* and *Dole*, the Court pointed out that it is a "gratuity" on the part of Congress to consent to an interstate compact and a "gift" to disburse funds to the states. The Court further explained: "In the present case, however, what Congress threatens if the State refuses to agree to its condition is not the denial of a gift or gratuity, but a sanction: exclusion of the State from otherwise permissible activity. . . . we think where the constitutionally guaranteed protection of the States' sovereign immunity is involved, the point of coercion is automatically passed—and the voluntariness of waiver destroyed—when what is attached to the refusal to waive is the exclusion of the State from otherwise lawful activity."[109]

It appears the "condition" the Court refers to is that the state waive its immunity, and "what Congress threatens" if the state refuses to agree to that condition is "exclusion of the state from otherwise permissible activity," namely, the exercise of rights under the Lanham Act. The Court, therefore, seems to be saying that a state's waiver of its immunity in response to a Congressional threat to be excluded from the otherwise lawful exercise of intellectual property rights would not be voluntary, and so would not be a valid Eleventh Amendment waiver. If that is the Court's view, it does not bode well for the Intellectual Property Restoration Act.[110]

Implications for Technology Transfer

The Intellectual Property Restoration Act, if enacted, would have immense implications for technology transfer at public universities. The implications arise primarily from the act's requirement that a state, as a whole, must waive its sovereign immunity before any part of the state could fully enforce its intellectual property rights.

If the act were became law, would states be willing to waive their sovereign immunity from intellectual property infringement suits? Among state entities, public universities and their technology transfer programs benefit most directly from full participation in the intellectual property system. Thus, it seems likely that public universities would be the strongest advocates within the states for waiver. A state as a whole, however, might well conclude that the financial liability avoided by sovereign immunity from infringement is worth more than the financial earnings from its public universities' technology transfer programs. But such a narrow economic calculation, in itself extremely complex, would surely not be the only dimension of a state's decision making on this issue.

Other dimensions might include the effect on the public universities' ability to recruit and retain faculty, how the state's overall business climate would be affected, the extent to which the state had already waived its sovereign immunity from claims against it in its own courts,[111] and, perhaps most incalculable of all, the states' rights issue: the state's willingness to accede to Congress' assertion of federal power over state sovereignty. Each state would be faced with a complex public-policy question with many dimensions, and it is far from clear how states would respond.

What would happen to technology transfer at a state's public universities if the act were to pass and the state does not waive its immunity? In that case, although injunctions would still be available, neither the state university nor the university's licensees or assignees would be able to sue for money damages for infringement of any "postcritical-date" intellectual property of which the university is or was the legal or beneficial owner. The effect this would have on technology transfer at public universities would probably be devastating. The precise contours the wreckage would take are difficult to predict, but one can reasonably hazard a few broad conjectures.

First, it would make it more difficult for public universities to protect their intellectual property rights. Despite the availability of injunctions, the costs of the legal action necessary to obtain an injunction, combined with the unavailability of a money damage award, would significantly raise the bar against such actions.

Second, exclusive licensing, as currently practiced, would probably no longer be viable. Without the availability of damage awards, few, if any, companies would likely be willing to take an exclusive license to a public university's technology. For companies that would otherwise take exclusive licenses, this would represent a loss of economic opportunity. That, in turn, would probably mean technologies that commonly require market exclusivity to be commercially viable, such as pharmaceuticals, would not be deployed from public universities for the public benefit.

Third, nonexclusive licensing would be undermined but probably not altogether eliminated. In many cases, a company probably would be unwilling to pay for a nonexclusive license to university technology when the university's only remedy for infringement would be to seek an injunction to stop it.

The act raises many other questions as well. Would it affect public universities' ability to obtain federal research grants? How would it affect research sponsorship from private commercial entities? How would it affect public universities' ability to promote economic development in their respective states? What would the effects be on private universities and commercial entities that license university technology? None of these questions has a clear answer at this time.

Conclusion

The Intellectual Property Restoration Act, as proposed in the 106th, 107th, and 108th Congresses, was a unique convergence of three fundamental issues. For the technology transfer community, the act presented the issue of state liability for intellectual property infringement—the "fairness" of states being immune and the competition between states and private business and private universities. For Congress, the act presented a power struggle with an activist Supreme Court whose decisions have diminished Congress'

power and overruled Congress' legislative choices. For the nation as a whole, the act was an instance of the states' rights issue: the tension, inherent in the Constitution and the nation's federal structure, between the power of the states and the power of the national government. Time may show that the way these issues converged in the aftermath of *Florida Prepaid* and *College Savings* was unique and transient, but these issues can be neither avoided nor fully resolved. The unfolding attempt to address them, whether in combination or singly, and whether at the level of the Congress, the states, or the universities, will shape the future of technology transfer.

Notes

1. *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank,* 527 U.S. 627 (1999).
2. *College Savings Bank v. Florida Prepaid Postsecondary Education Expense Board,* 527 U.S. 666 (1999).
3. Two such bills were most recently introduced in the 108th Congress: S. 1191, 108th Cong. (2003); and H.R. 2344, 108th Cong. (2003).
4. See generally John J. Gibbons, "The Eleventh Amendment and State Sovereign Immunity: A Reinterpretation," 83 *Col. L. Rev.* 1889, 1899-1914 (1983) (hereafter "Gibbons").
5. *Alden v. Maine,* 527 U.S. 706, 715 (1999) (citing 1 W. Blackstone, *Commentaries on the Laws of England* 234-235 [1765]).
6. Article III of the Constitution defines the judicial powers of the United States. Articles I and II define the powers of Congress and the executive branch, respectively.
7. E.g., *The Federalist No. 81* (A. Hamilton) (emphasis original), available at http://www.yale.edu/lawweb/avalon/federal/fed.htm; 3 *The Debates in the Several State Conventions of the Adoption of the Federal Constitution,* Vol. 3, p. 533 (J. Elliot ed. Philadelphia 1866) (hereafter "Elliot's Debates"), available at: http://memory.loc.gov/ammem/amlaw/lwed.html.
8. 3 Elliot's Debates, at 543 (Mason) and 527 (Henry).
9. See generally Erwin Chemerinsky, *Constitutional Law* 185-190 (2002) (hereafter "Chemerinsky") (a brief overview of the two views); Gibbons, 83 *Colum. L. Rev.* 1889 (detailed historical treatment of the issue); John T. Noonan Jr., *Narrowing the*

Nation's Power 58-85 (2002) (arguing that state immunity was not part of the constitutional design); James F. Simon, *What Kind of a Nation* (2002) (general history of early struggles to balance federal powers and states' rights).

10. 2 Dall. (2 U.S.) 419 (1793).
11. The Judiciary Act of 1789, ch. 20, §13, 1 Stat. 73, 80.
12. Charles Warren, 1 *The Supreme Court in United States History* 101 (Little, Brown, rev. ed. 1932).
13. Id. 1 Elliot's Debates, at 341.
14. 134 U.S. 1 (1890).
15. Id. at 9.
16. Id. at 17 (quoting *Beers v. Arkansas),* 61 U.S. (20 How.) 527 (1858).
17. 527 U.S. 706 (1999).
18. Id. at 728.
19. Id. at 714.
20. Id.
21. Id.
22. Id. (quoting *Printz v. United States,* 521 U.S. 898, 919-920 [1997]).
23. 209 U.S. 123 (1908).
24. U.S. Const. art. VI, cl. 2.
25. Ex *Parte Young,* 209 U.S. at 159-160.
26. E.g., *Kentucky v. Graham,* 473 U.S. 159, 166-67 (1985) (Eleventh Amendment is no defense to a charge against an official in his personal capacity). The distinction between "individual" and "official" capacity suits often turns on whether recovery is sought from the individual's personal resources or from the state treasury. See, e.g., *Hafer v. Melo,* 502 U.S. 21, 25 (1991) (an "individual capacity" suit seeks "to impose individual liability upon a government officer for actions taken under color of state law"); *Edelman v. Jordan,* 415 U.S. 651, 675 (1974) (a suit seeking a judgment to be paid from the public treasury is an official capacity suit and barred); *Pennhurst State School and Hospital v. Halderman,* 465 U.S. 89, 101-02, n. 11 (1984) (the Eleventh Amendment is bar when "the state is the real substantial party in interest," that is, when "the judgment sought would expend itself on the public treasury…or interfere with the public administration"). However, an individual capacity suit

against a public official, although not barred by the Eleventh Amendment, may be barred by common law immunities, such as "qualified immunity." *Harlow v. Fitzgerald*, 457 U.S. 800, 818 (1982) (public officials sued in their individual capacities are entitled to qualified immunity when their actions do not violate "clearly established statutory or constitutional rights"); *Lane v. First National Bank of Boston,* 687 F. Supp. 11, 15-18 (D. Mass. 1988) (qualified immunity available as defense in suit alleging copyright violations, but public officials not entitled to the immunity because right they allegedly violated was clearly established); *Tapley v. Collins,* 211 F.3d 1210, 1214-15, n. 9 (11th Cir. 2000) (qualified immunity is available as defense in suit alleging violations of Federal Electronic Communications Privacy Act). Cf. *Blaylock v. Schwinden,* 862 F.2d 1352, 1354 (9th Cir. 1988) (state indemnification requirements do not affect whether a suit is an official capacity suit). See generally Chemerinsky, at 207-208 (discussing official and individual capacity suits and common law immunities); W. Page Keeton, ed., *Prosser and Keeton on the Law of Torts* (5th ed. 1984) 1032-69 (immunities of states and public officials).

27. *United States v. Mississippi,* 380 U.S. 128, 140-141 (1965). On whether Congress could authorize a private party to sue on behalf of the federal government in a qui tam action, see *Vermont Agency of Natural Resources v. United States* ex rel. Stevens, 529 U.S. 765, 787 (2000) (expressing doubt "whether an action in federal court by a qui tam relator against a State would run afoul of the Eleventh Amendment").
28. *South Dakota v. North Carolina,* 192 U.S. 286, 315-21 (1904); *Colorado v. New Mexico,* 459 U.S. 176, 182 n. 9 (1982).
29. *Mt. Healthy City School District Board of Education v. Doyle,* 429 U.S. 274 (1977).
30. *Pennhurst State School & Hospital v. Halderman,* 465 U.S. 89, 123-124 (1979).
31. The courts use a variety of factors for such determinations, such as the entity's source of funding, the extent of state control over the entity's decisions and actions, whether the entity's head is appointed by the state executive or legislature, and how the entity is characterized under state law. See John R. Pagan, "Eleventh Amendment Analysis," 39 *Ark. L. Rev.* 447, 461 (1986) (identifying criteria courts rely on to decide whether a state-related entity receives Eleventh Amendment immunity) (hereafter "Pagan"). See generally Chemerinsky, at 195-197.

32. E.g., *Regents of the University of California v. Doe,* 519 U.S. 425 (1997); *Clay v. Texas Women's University,* 728 F.2d 714 (5th Cir. 1984); *Jackson v. Hayakawa,* 682 F.2d 1344 (9th Cir. 1982); *Xechem International, Inc. v. The University of Texas M.D. Anderson Cancer Center and Board of Regents,* 382 F.3d 1324 (Fed. Cir. 2004) (upholding district court's dismissal on Eleventh Amendment grounds of company's action to correct inventorship under 35 U.S.C. §256 against the board of regents of the University of Texas system), cert denied, 125 S. Ct. 1314, — U.S. — (2005); cf. *Hander v. San Jacinto Junior College*, 522 F.2d 204, 205 (5th Cir. 1975) (Texas junior college districts are independent political subdivisions not immune for Eleventh Amendment purposes). See generally Pagan, at 461.
33. E.g., *Florida Dept. of Health & Rehabilitative Services v. Florida Nursing Home* Assn., 450 U.S. 147, 149-150 (1980).
34. E.g., *Kennecott Copper Corp. v. State Tax Commission,* 327 U.S. 573, 578-580 (1946).
35. *Atascadero State Hospital v. Scanlon,* 473 U.S. 234, 241 (1985).
36. Id. at 238.
37. 377 U.S. 184 (1964), overruled by *College Savings Bank v. Florida Prepaid Postsecondary Education Board,* 527 U.S. 666, 680 (1999).
38. *Parden,* 377 U.S. at 192.
39. 411 U.S. 279, 285 (1973).
40. 415 U.S. 651, 673 (1974).
41. 483 U.S. 468, 478 (1987).
42. 527 U.S. 666 (1999).
43. Id. at 676.
44. Id. at 680.
45. 427 U.S. 445 (1976).
46. 390 F. Supp. 278 (D. Conn. 1974).
47. *Fitzpatrick,* 427 U.S. at 454.
48. 491 U.S. 1 (1989), overruled by *Seminole Tribe of Florida v. Florida,* 517 U.S. 44, 66 (1996).
49. *Atascadero State Hospital v. Scanlon*, 473 U.S. 234, 242 (1985).
50. *Union Gas,* 491 U.S. at 13.

51. U.S. Const. art. I, sec. 8, cl. 3.
52. *Union Gas,* 491 U.S. at 13-23.
53. Pub. L. No. 101-553, 104 Stat. 2749 (1990) (codified at 17 U.S.C. §§501(a), 511); see generally M. Nimmer and D. Nimmer, *Nimmer on Copyright* §12.01[E][2][b], at 12-48 (Congress enacted CRCA "[b]ased on *Union Gas*' conclusion that Congress may, in the exercise of its Article I authority, abrogate state Eleventh Amendment immunity").
54. Pub. L. No. 102-542, 106 Stat. 3567 (1992) (codified at 15 U.S.C. §§1122, 1125[a]).
55. Pub. L. 102-560 (codified at 35 U.S.C. §§271[h], 296[a]).
56. For example, section 43(a) of the Lanham Act (15 U.S.C. §1125[a]), as originally enacted in 1946, created a private right of action against "[a]ny person" who uses false descriptions or makes false representations in commerce. The TRCA amended §1125 by redefining "any person" to include states and their instrumentalities and employees acting in official capacities. 15 U.S.C. §1125(a)(2).
57. 517 U.S. 44 (1996).
58. 25 U.S.C. §2702 et seq.
59. The Indian Commerce Clause is a subpart of Const. art. I, sec. 8, cl. 3, which also grants Congress' power to regulate commerce between the states.
60. 25 U.S.C. §2710(d)(3)(A).
61. 25 U.S.C. §2710(d)(7).
62. 517 U.S. at 59-63. The Court also went further and created an exception to the *Ex Parte Young* doctrine. The relief the tribe was seeking was prospective: an order from the federal court requiring Florida to negotiate a compact. This would have seemed to have been a situation where the theory of *Ex Parte Young* would apply. Insofar as state officials were acting contrary to federal law, they were stripped of their official status and could not assert the Eleventh Amendment as a defense. But the Court declined to apply this approach, and held instead that state officers cannot be sued to enforce federal regulations that contain comprehensive enforcement mechanisms. 517 U.S. at 73-76.
63. 521 U.S. 507 (1997).
64. 494 U.S. 872 (1990).
65. 521 U.S. at 516-17.

66. Id. at 519.
67. Id. at 516-529.
68. 5 U.S. 137 (1803). See Chemerinsky, at 39: "*Marbury v. Madison* is the single most important decision in American constitutional law."
69. 521 U.S. at 516.
70. Id. at 520.
71. *College Savings Bank v. Florida Postsecondary Expense Savings Board,* 948 F. Supp. 400 (D. N.J. 1996).
72. Id.
73. *College Savings Bank v. Florida Postsecondary Expense Savings Board,* 131 F.3d 353 (3rd Cir. 1997); *College Savings Bank v. Florida Postsecondary Expense Savings Board,* 148 F.3d 1343 (Fed. Cir. 1998).
74. 527 U.S. 627 (1999).
75. Id. at 646-47.
76. 527 U.S. 666 (1999).
77. Id. at 675.
78. *State Sovereign Immunity and Protection of Intellectual Property,* Hearing before the Subcommittee on Courts and Intellectual Property of the House Committee on the Judiciary, 106th Cong. 20 (July 27, 2000) (hereafter "July 2000 Hearing") (statement of Todd Dickenson, undersecretary of commerce for Intellectual Property and director of the United States Patent and Trademark Office, United States Department of Commerce), July 27, 2000.
79. See *Chavez v. Arte Publico*, 204 F.3d 601 (5th Cir. 2000) (CRCA is unconstitutional because it fails as remedial legislation). See generally Nimmer §12.01[E][2][b].
80. July 2000 Hearing, at 54 (statement of Marybeth Peters, register of copyrights, Copyright Office of the United States, Library of Congress).
81. 528 U.S. 62 (2000).
82. 531 U.S. 356 (2001).
83. 535 U.S. 743 (2002).
84. 538 U.S. 721, 123 S. Ct. 1972, 155 L. Ed. 2d 953 (2003).
85. 541 U.S. 509 (2004).
86. The first bill, S. 1835 in the 106th Congress, was introduced by Sen. Patrick Leahy of

Vermont in October 1999. With extensive findings and purposes, S. 1835 would have provided that no state could acquire a federal intellectual property right without first opting into the federal intellectual system by waiving sovereign immunity. The bill also aimed to abrogate state immunity to the maximum extent permitted under the Constitution. In the 107th Congress, in November 2001, Leahy introduced a new bill, S. 1611, that followed the same general approach as his bill of two years previous—requiring states to waive as a condition of exercising intellectual properties rights—but which was greatly revised. A companion bill to S. 1611, H.R. 3204, was also introduced at that time by Rep. Howard Coble of North Carolina. Later in the 107th Congress, Leahy introduced the same text as a new bill, S. 2031, on March 19, 2002, co-sponsored by Sen. Sam Brownback of Kansas. The two bills now pending in the 108th Congress, S. 1191 and H.R. 2344, were both introduced on June 5, 2003, in the Senate by Leahy and in the House by Lamar Smith of Texas and co-sponsored by Howard Berman of California and John Conyers Jr. of Michigan. S. 1191 and H.R. 2344 are textually the same bill. They differ from the bills in the 107th Congress only in that the states are given relatively longer time periods to waive their immunity than was allotted them under the 107th Congress bills.

87. Cong. Rec. S7479, June 5, 2003.
88. Id.
89. Cong. Rec. S7480, June 5, 2003. This issue of fairness has been a recurrent theme in hearings regarding the *Florida Prepaid* decisions. At a hearing on July 27, 2000, before the House Subcommittee on Courts and Intellectual Property, Rep. Howard Berman of California described the necessity of correcting the "unfairness and imbalance in Federal law" created by *Florida Prepaid* and *College Savings Bank:* "After those decisions, states can infringe the intellectual property rights of others with virtual impunity, while still enforcing their own intellectual property rights against all others. This situation is made doubly unfair by virtue of the fact that states often engage in for-profit enterprise and direct competition with private actors. States run publishing houses, radio stations, restaurants, and hospitals, develop drugs, medical technologies, and commercial software products, and sell a variety of merchandise. To the extent that they do not have to license or otherwise pay for intellectual property rights when running these businesses, states have a

competitive advantage over private actors. That is not right, even though my alma mater, University of California, would be among the largest of these owners of intellectual property. Furthermore, to the extent that states can enforce their intellectual property rights against competitors but need not fear infringement suits themselves, states have an additional competitive advantage." July 2000 Hearing, at 12 (statement of Howard L. Berman, member Subcommittee on Courts and Intellectual Property).

90. Cong. Rec. S7480, June 5, 2003.
91. Id.
92. *U.S. Government Accounting Office, State Immunity in Infringement Actions,* GAO-01-811 (2001) (hereafter "GAO Report") (available at: http://www.gao.gov).
93. GAO Report, at 2.
94. Register of Copyrights Marybeth Peters presented these possible approaches to the House Subcommittee on Courts and Intellectual Property at the July 2000 Hearing. See July 2000 Hearing, at 56-64. Peters also identified two additional approaches: Congressional enforcement under Section 5 of the Fourteenth Amendment and the approach embodied in Leahy's bills. She expressed support for the approach in the Leahy bills. See July 2000 Hearing, at 64.
95. The 1999 version of the bill, S. 1161 (106th Cong.), required waiver before a state could obtain a patent or the registration of a copyright or trademark.
96. S. 1191, 108th Cong. §3. Because S. 1191 and H.R. 2344 are parallel bills, only the citations for S. 1191 will be provided here.
97. Id.
98. Id. §§4, 5. A state's waiver of its immunity would not affect the applicability of these provisions to the state.
99. Id. §3.
100. Id.
101. Id.
102. Id.
103. See *Sovereign Immunity and the Protection of Intellectual Property,* Hearing before the Senate Committee on the Judiciary, 108th Cong. (2003) (statement of William E. Thro, general counsel, Christopher Newport University, and special assis-

tant attorney general, Commonwealth of Virginia), available at http://www.nacua.org/documents/IP_Restoration_Act_Statement-Thro.htm.

104. *South Dakota v. Dole,* 483 U.S. 203 (1987). Cf. *Atascadero State Hospital v. Scanlon,* 473 U.S. 234, r'hg denied 473 U.S. 926 (1985) (Congress may require waiver of Eleventh Amendment immunity as condition for participation in federally funded program, but a state's receipt of funds does not alone constitute waiver).
105. 359 U.S. 275 (1959). Article I, §10, cl. 3 of the Constitution prohibits states from entering into compacts with one another without the consent of Congress.
106. E.g., *New York v. United States,* 505 U.S. 144, 166 (1992) (Congress may "hold out incentives to the States as a method of influencing a State's policy choices"); see generally July 2000 Hearing, 100-112 (statement of Howard J. Meltzer, Harvard Law School).
107. *College Savings,* 527 U.S. at 680.
108. Id. at 686.
109. Id. at 687.
110. Cf. *New York v. United States,* 505 U.S. 144 (1992) (Congress violates the Tenth Amendment by compelling state legislatures to adopt laws or state agencies to adopt regulations).
111. Some states, such as Washington, have broadly waived their immunity and subjected themselves to the same liability in their own courts as may be found against individuals and corporations. Wash. Rev. Code 4.92.090. Other states, such as Pennsylvania, assert sovereign immunity with such exceptions as the legislature may declare. 1 Pa. C.S. §2310.

Madey v. Duke University and Other Important Patent Issues Affecting University Research

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This section will explore several important patent issues that can uniquely impact university research, as well as how universities and their respective technology transfer offices can respond to these issues. This section discusses many cases where universities were involved in these issues, such as *Madey v. Duke University.*

Defenses to Infringement

The best defense to patent infringement is to avoid the issue entirely. However, that may not always be possible. Eventually, a university may have to confront a patent infringement problem. Rather than simply paying royalties or altering the research program, a university may be able to assert one of the following established defenses to patent infringement.

The Experimental Use Defense[1]

The best-known and possibly least useful defense to patent infringement is the experimental use defense.[2] The experimental use defense can be viewed as roughly the patent law equivalent of the fair use doctrine of copyright law,[3] and has been in existence since 1813.[4] The experimental use defense has two branches. The first branch is known as the *ascertain validity branch,*[5] and holds that one is entitled to practice the patented invention in order to check and test the validity of the patent.[6] While there is little case law on the ascertain validity branch,[7] it remains as an extremely viable defense to patent infringement.[8]

The other, more commonly relied on branch, is known as the *philosophical experiment branch* and applies to those situations where the alleged infringement is "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[9] Until 2003, it was thought that the philosophical experiment branch of the experimental use defense

would cover any research, including academic research, of a noncommercial nature. However, in the 2003 case of *Madey v. Duke University*,[10] the Court of Appeals for the Federal Circuit virtually negated that possibility.

In *Madey,* the Federal Circuit reaffirmed its admonition in two prior cases, *Roche Products, Inc. v. Bolar Pharmaceutical Co.*[11] and *Embrex, Inc. v. Service Engineering Corp.*[12] that the experimental use defense is extremely narrow and "does not immunize any conduct that is in keeping with the alleged infringer's legitimate business," even if that conduct is of a noncommercial nature. As long as the university's research projects "further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects," the experimental use defense does not apply.

Universities may still be able to assert the experimental use defense for one-time academic research experiments that infringe someone else's patent. However, unless Congress intervenes by statute (unlikely at this time),[13] universities generally should not rely on the experimental use defense to protect ongoing academic research against patent infringement, even if that research can be considered to be noncommercial in nature. As discussed below, there are much better, more reliable defenses to consider. These other defenses are also potentially applicable to not only noncommercial, university research, but also to university research that is or could be considered commercial in nature.

Sovereign Immunity under the Eleventh Amendment[14]

For research carried out at state universities, there is an extremely powerful defense against patent infringement: sovereign immunity under the Eleventh Amendment. Indeed, sovereign immunity under the Eleventh Amendment does not even require that the university research be for other than commercial purposes, a key requirement for the experimental use defense to apply.

In 1992, Congress tried to abrogate the states' sovereign immunity under the Eleventh Amendment against patent infringement suits in federal district court. In 1999, the Supreme Court, by a slim majority (5-4), ruled in *Florida Prepaid Postsecondary*

Education Expense Board v. College Savings Bank that Congress did not properly abrogate the states' sovereign immunity under the Eleventh Amendment against such patent infringement suits.[15]

As long as Congress is unable to abrogate the states' sovereign immunity under the Eleventh Amendment,[16] state universities[17] can be fairly confident that their research, whether for commercial or noncommercial purposes, is secure against patent infringement suits in federal district court. Even so, state universities still need to guard against certain instances where the university's "voluntary participation" in a lawsuit in federal district court for other reasons could be held to waive sovereign immunity under the Eleventh Amendment against a patent infringement claim.[18] For example, waiver could occur in a dispute between the state university and its faculty member(s) over who owns the patent rights in the particular academic research.[19]

In the 2004 case of *Xechem International, Inc. v. The University of Texas M.D. Cancer Center,* the Federal Circuit reaffirmed that waiver of sovereign immunity by a state university must be truly voluntary.[20] The Federal Circuit also hinted in *Xechem* that the current efforts by Congress to abrogate state immunity against patent infringement could again be attacked on constitutional grounds. Even so, cases like *Xechem* point out the possible danger of a state university potentially waiving its sovereign immunity under the Eleventh Amendment when litigating in federal district court to enforce its intellectual property rights.

The Hatch-Waxman Act

For private universities, the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act)[21] might provide an alternative defense for certain academic research against patent infringement. The Hatch-Waxman Act provides immunity from suit where the testing of the patented invention is for the purpose of securing regulatory approval from the Food and Drug Administration (FDA).[22] Originally, it was believed that the Hatch-Waxman Act only applied to testing to secure regulatory approval of a patented drug. However, in *Eli Lilly & Co. v. Medtronic, Inc.,* the Supreme Court held that the immunity provided by the Hatch-Waxman Act also applied to medical devices.[23] Indeed,

the basis for the holding in *Medtronic* makes this immunity applicable to the testing of *any* patented invention (e.g., food additives, cosmetics, etc.) for the purpose of securing regulatory approval from the FDA.[24]

The immunity provided by the Hatch-Waxman Act was further expanded recently by court decision in the preclinical research area. In *Merck KgaA v. Integra Lifesciences I, Ltd.*, the Supreme Court reversed a ruling by the Federal Circuit that the immunity provided by the Hatch-Waxman Act did not apply to *preclinical* research, such as screening for potential drug candidates. Instead, the Supreme Court held in *Merck* that, as long as the preclinical research could potentially result in a submission to the FDA for regulatory approval, that was enough to shield such research from a patent infringement suit under Hatch-Waxman. Even more interesting and expansive were statements by the Supreme Court in *Merck* that such preclinical research would be protected by Hatch-Waxman, even if that research: (1) was for the purpose of developing new drugs or new uses of existing drugs or (2) the results of such research were later not submitted to the FDA to secure regulatory approval. In other words, as long as the preclinical research is "reasonably related" to potentially securing regulatory approval from the FDA, the "safe harbor" of Hatch-Waxman applies. This could make the protection of Hatch-Waxman of increasing value to universities in immunizing their preclinical research against patent infringement where such research has at least an arguable basis for being used in a submission to the FDA to secure regulatory approval.

Federally Sponsored Research

One potential safe harbor tantalizing raised, but left unresolved by the *Madey* case, is whether federally sponsored university research is immunized from patent infringement under 28 U.S.C. §1498(a).[25] Basically, 28 U.S.C. §1498(a) provides that the only remedy for patent infringement by the United States is "reasonable compensation" (i.e., the infringing activity cannot be enjoined by the courts), and then only by filing a lawsuit in the United States Court of Claims. It also provides complete immunity for federal contractors who undertake such allegedly infringing activity for the United States and is, therefore, referred to as the *federal contractor's defense.*[26]

Unfortunately, the Federal Circuit in *Madey* only vaguely defined what the scope and requirements would be for a university to come under the protective umbrella of the federal contractor's defense. From what was briefly said in *Madey,* it is doubtful the Federal Circuit will apply this defense to every instance of federally funded research carried out at a university. Instead, the Federal Circuit suggests that the terms of the research grant from the respective federal agency will control and will be scrutinized to see if the university's research is "by or for the United States" and has the "authorization and consent" of the federal government. Because the *Madey* case was returned to the district court for further proceedings (and may be subsequently reviewed by the Federal Circuit), there will hopefully be further clarification of how 28 U.S.C. §1498(a) would apply to federally funded university research.

Publication, On Sale, and Public Use Bars

As universities realize, most of academia exists in a publish-or-perish environment. That means there is significant pressure, either by policy or by the researcher, to permit prompt publication of journal articles by university researchers and to allow presentations on significant research results at various scientific meetings. Unfortunately, if fully supported and enabled patent applications are not filed beforehand, the patent rights in such significant research may be lost immediately in many countries outside the United States and, eventually, in the United States after the passage of a year from the time the research results are published or shared at a scientific meeting. Even university clinical or other research studies can cause the eventual loss of patent rights if such work is published or otherwise disseminated publicly. This makes it incumbent upon universities to put systems in place to anticipate such publications, presentations, and studies or to at least minimize the potential loss of patent rights that can be caused thereby.

General Rules: When Does Publication or Other Public Dissemination of Research Results Bar Patenting?

Most, if not all countries, outside the United States have adopted the standard that any publication or other public dissemination of the invention to others not under an obligation of confidentiality[27] will cause a loss of patent rights in that invention unless a patent application covering that invention is filed beforehand. This is commonly referred to as

the *absolute novelty standard.* Europe is a prime example of a region that has adopted this strict standard for novelty.[28]

As the name suggests, the absolute novelty standard has no grace period for filing the patent application after publication or other public dissemination of the invention has occurred. Under an absolute novelty standard, this loss of patent rights occurs even if the publication or other public dissemination is by the inventor. There are some countries, such as Canada, that supposedly apply an absolute novelty standard, but still provide up to one year to file the patent application after publication or other public dissemination by the inventor.

By contrast, the United States has a grace period of up to one year to file the patent after publication thereof anywhere in the world or after the invention is in public use or on sale in the United States.[29] These are commonly referred to as *statutory bars* to patenting of the invention. Naturally, there has been a significant amount of case law on what constitutes publication, public use, or on sale of the invention that can cause such a statutory bar to run. Of particular interest to universities are some recent cases that have considered: (1) when does a presentation at a scientific meeting become a publication? (2) when does research, such as clinical studies, become a public use? and (3) what is the difference between offers for sale and offers for license of the technology?

Presentations at Scientific Meetings as Publications[30]

In *In re Klopfenstein,* [31] the Federal Circuit recently clarified when a presentation at a scientific meeting can become a publication. In prior cases involving college theses and presentations to faculty members, there had been some confusion as to whether publication was determined by the degree to which the thesis/presentation had been disseminated/distributed and/or whether it had been appropriately indexed in the university library or database.[32]

The Federal Circuit held in *Klopfenstein* that the key inquiry was whether or not the alleged publication was publicly accessible. In determining whether the alleged publication was publicly accessible, the Federal Circuit articulated three factors to consider: (1)

whether the alleged publication was shown for an extended period of time to members of the public having the relevant level of knowledge (i.e., those of "ordinary skill in the art"); (2) whether those members of the public were precluded from taking notes or even photographs of the alleged publication; and (3) whether the alleged publication was presented in such a way that copying of the information it contained would be a relatively simple undertaking for those to whom it was exposed.[33]

In a footnote, the Federal Circuit in *Klopfenstein* said that an entirely oral presentation at a scientific conference that included neither slides, nor copies of the presentation would not be considered a publication.[34] Even so, such an oral presentation might still be considered a public use of the invention and thus cause a statutory bar to occur.[35] Accordingly, universities should still review and clear such presentations to scientific meetings, whether the presentation is to be printed or oral.[36]

Clinical Studies or Other Research as Public Use

Clinical studies and other research at a university may eventually create a public use statutory bar. Whether an invention is in public use is based primarily on two factors: (1) was the alleged use public and (2) did the invention exist in a sufficiently definable form at the time of the alleged use. The first factor is typically (but not always) determined by whether the alleged use was kept secret or was under an obligation of confidentiality (thus negating public use) or whether the alleged use was without restriction (thus implying public use).

The second factor is determined by whether the invention is ready for patenting. Typically, an invention is ready for patenting when, for example, at least a prototype of the invention has been made, i.e., there has been a reduction to practice. However, in the 1998 case of *Pfaff v. Wells Electronic, Inc.,* the Supreme Court ruled that an invention could be ready for patenting if the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention.[37]

The *Pfaff* case involved an offer for sale of the invention, not a public use. In addition, the patentee not infrequently argues that the alleged use involved testing of the invention, making the use experimental and, therefore, not a public use. In the 2004 case of *SmithKline Beecham Corp. v. Apotex Corp.,*[38] the Federal Circuit initially put a significant cloud over whether clinical studies were experimental and, thus, not a public use. In *SmithKline,* a patented drug had been placed in clinical trials more than one year prior to the filing of the patent application "to establish that the [patented drug] actually worked (and was safe) as an antidepressant." The Federal Circuit ruled that this clinical testing: (1) only measured the safety and efficacy of the patented drug as an antidepressant; (2) was not needed to define what was claimed, i.e., the drug itself; and (3) was, therefore, not experimental, but was instead an invalidating public use.

Recently, the entire Federal Circuit (en banc) vacated the original holding in the *SmithKline* case based on the clinical study being an invalidating public use.[39] Even so, the *SmithKline* case would suggest caution in relying on all university research (especially clinical studies) as being experimental. It would further suggest that patent filing should be done sooner rather than later, especially if such research is discussed or otherwise disseminated to anyone outside the university, e.g., at a scientific meeting.

Offers for Sale v. Offers for License

There is an important distinction between *offers for sale* of the invention that can create an on sale statutory bar, and *offers for license* of the rights in the invention that do not. Understanding this important distinction can be extremely valuable to universities that rely on licensing their patent/invention rights to secure significant income.

As the case law makes clear, offers for sale that qualify as an on sale statutory bar must be of a *tangible item,* e.g., a device, product, drug, etc.[40] By contrast, if the offer is for selling, conveying, or licensing the *intangible rights* in the invention, including patent rights, that does not place the invention on sale.[41] *Most importantly,* payment in the form of royalties in exchange for the license does not change it into a sale or offer for sale of the invention. Some examples of such offers for license or their equivalents include: (1) a conveyance of production rights in the invention, (2) an exclusive right to market

the invention, and (3) granting a license under a patent and offering to help in clinical testing and eventual marketing of the invention.[42] Indeed, for technology involving processes or methods, the Federal Circuit in *In re Kollar*[43] has pointed out the difficulty, if not impossibility, of having an on sale bar occur by selling the know-how or details of how the process or method is to be carried out.[44]

In the 2004 case of *Elan Corp. v. Andrx Pharmaceuticals, Inc.*,[45] the Federal Circuit has reaffirmed that an offer for license of the technology or its equivalent does not create an on sale statutory bar. The *Elan* case is also significant in that the letter that contained the offer for license further included a reference to a pricing structure for eventually supplying bulk quantities of the invention, i.e., drug tablets. This might have suggested that more than an offer for license was involved, i.e., pricing for sale of the tablets. However, the Federal Circuit ruled that this was insufficient to put the invention on sale because it could not be determined what the offering price would be until several other things were known, including the final drug formulation, as well as the cost of the active ingredient, packaging, and processing.

The *Elan* case and its predecessors should provide a great deal of comfort to university technology transfer offices when licensing their technology. Universities are usually not in a position to offer commercial terms for eventual sale of tangible embodiments of the invention, so the risk of an accidental on sale statutory bar occurring in the license, or even sale, of university technology is even more remote than for commercial businesses. If the invention involves a process or method technology, the risk of triggering an on sale statutory bar by licensing such technology is almost nonexistent.

Managing Inventors, Inventorship, and Ownership of Patents

Every university understands the importance of having prolific and innovative inventors. The relationship between the inventor and the university is one of the most critical links in the patenting process. The university must maintain this relationship to (a) obtain valid patents, (b) encourage and reward further inventive research, (c) have valid title to the patents in order to license or otherwise transfer rights in the technology, and (d) know when others could be or are infringing university patents.

Three aspects of inventorship are important to universities: (1) identifying who the inventor is, (2) obtaining valid title from the identified inventor, and (3) determining what obligations does the university owe, if any, to the inventor in obtaining title. Universities need to be aware of these inventorship issues to avoid easy challenges to the validity and ownership of university patents.

Correctly Identifying Inventors

Universities may assume that identifying the correct inventor is nothing more than an administrative task because those submitting the invention disclosure are most likely to be the inventors. However, inventorship is actually a question of law, which is uniquely relevant to United States patents.[46] Incorrect inventorship can invalidate the patent unless it can later be corrected. Unfortunately, if the erroneous inventorship occurred as the result of deceptive intent, it cannot be corrected, making the patent invalid and unenforceable.[47]

While inventorship of the patent is not questioned in most situations, the potentially significant consequences of incorrect inventorship make it important to correctly identify the inventors at the time the patent is applied for. For this reason, the determination of inventorship should be the responsibility of the registered patent attorney (or agent) who is drafting the patent application. The patent attorney has the education and training to correctly identify inventors based on established legal criteria. The patent attorney can also provide an objective and unbiased determination that may be corrected, if necessary, because of a later inventorship challenge. While university patent managers can be helpful in identifying prospective inventors, the ultimate determination of inventorship should still be left to the patent professional.

Most university researchers, as well as some university managers, confuse the concept of *inventorship* in patent law with the concept of *authorship* in copyright law. Inventorship requires a determination of who contributed to the *claimed* invention based on a consideration of two factors: (1) conception and (2) reduction to practice. Because *non-inventors* may reduce an invention to practice, inventorship is more typically determined by who participated in the conception.[48] Even so, reduction to practice may result in an inventive contribution to the invention and should be considered in the inventorship review process.

Conception occurs "when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation."[49] Where conception is the joint contribution of two or more individuals, it is not necessary to determine who contributed exactly what component of the conception, "but one must be able to say that without his contribution to the final conception, it would have been less—less efficient, less simple, less economical, less something of benefit."[50] Inventorship can sometimes be resolved by asking simple questions such as: What were the contributions of each alleged inventor? When did each alleged inventor contribute to the invention? But this is not always the case. Instead, each researcher should be interviewed about what they did on the project.

Collaborative relationships between industry and university researchers are familiar to all of those involved in university patent practice. Unfortunately, these collaborative relationships can complicate and obscure the identification of who conceived the invention and should, therefore, be named as the inventor(s) on the patent. Most university researchers also do not understand that what they communicate to an industry collaborator may end up in a patent. That the university and the industry collaborator may have competing interests in what is communicated is also frequently lost on the university researcher.

The recent case of *University of Colorado Foundation, Inc. v. American Cyanamid Co.*[51] illustrates why universities need to be on their guard about inventorship when their researchers communicate with industry. In *University of Colorado Foundation,* two university doctors conducted several studies on a prenatal supplement for iron deficiency in pregnant and lactating women. The doctors then communicated with the chief of nutritional science at American Cyanamid, a long-time colleague, and suggested reformulation of the supplement. American Cyanamid became interested in the doctors' research and asked them to conduct two additional studies using the reformulated supplement.

Prior to publishing their results, the doctors sent a confidential manuscript to American Cyanamid. American Cyanamid later filed for a patent naming its chief of nutritional science as the sole inventor. The unnamed doctors later received a copy of the issued

patent and noticed that their confidential material was part of the patent. The University of Colorado then filed suit, challenging the inventorship of the patent.

The Federal Circuit affirmed the ruling of the lower court that the university doctors should have been named as the inventors because they had conceived the invention and described it with sufficient particularity in their communication to the chief of nutritional science. That the chief of nutritional science reviewed the findings of the university doctors and then recommended further study was not enough to make his contribution inventive. The additional two studies (the reduction to practice) that were carried out at his suggestion simply confirmed the original conception of the university doctors. The consequence for American Cyanamid's misdeeds was severe: a multimillion judgment against American Cyanamid for "unjust enrichment" because of its unauthorized use of the doctors' invention.

Another example of when an inventive contribution will not be regarded as joint inventorship is when the inventor made the contribution after the patent was filed. In *Oregon Health & Science University v. Vertex Pharmaceuticals, Inc.,*[52] a university researcher was carrying out testing of compounds under an agreement and discovered that nonbinders of FKBP 12 exhibited neurotropic effects previously believed to be characteristic of the binders. Vertex, who had filed for the patent on the binders only, then amended the filed patent to try to cover the later discovered nonbinders. Because the nonbinder subject matter was discovered after the patent was filed and because the university researcher who discovered it was not named as an inventor at the time the patent was originally filed, the court ruled there could be no joint inventorship.[53]

Taken together, the cases of *University of Colorado Foundation* and *Oregon Health & Science University* demonstrate that, for a joint inventive collaboration to exist, the joint conception of the individuals involved must occur at or around the same time. In particular, if someone's contribution occurs fairly late in the project's life, and especially after initial conception occurs, that individual's contribution is less likely to be inventive.[54]

There are several other situations where the collaboration between two or more individu- also is not a joint invention. These situations arise where one person follows someone

else's directions in reducing the invention to practice,[55] makes an obvious contribution or improvement,[56] merely suggests a result to be achieved,[57] knows only an insufficient portion of the invention,[58] provides publicly available information,[59] or contributes ideas that are part of the prior art.[60] However, as long as there is some communication or other appropriate collaborative involvement between the individuals that leads to a joint conception, joint inventorship can exist even though these individuals are not located in the same place or make different types or levels of contribution to the invention.

An omitted inventor can be added after the patent is granted, but that requires proof that the omission occurred without deceptive intent, as well as clear and convincing evidence of the omitted inventor's contribution.[61] This stringent standard can work against the university when seeking to add one of its researchers as an inventor to a patent so that the university can obtain an ownership interest therein.[62] The general rule of thumb of "when in doubt, and if there is a supportable basis, add the researcher" as an inventor will avoid having to deal with this problem of the omitted inventor and will usually provide a supportable basis for correcting inventorship later if that becomes necessary.

Obtaining Rights from University Inventors[63]

Once the inventors are properly identified and, preferably, shortly before or after the patent is filed, the university should next get a transfer (assignment) of title in the invention rights from the inventor. An assignment is not a requirement for filing or getting a patent. But without clear title to such rights from the inventor, the university's effort to interest and get potential licensees may be jeopardized. For example, in *Trustees of Boston University v. Beacon Laboratories Inc.,* the licensee was successful in showing that the university breached the license because the university did not secure rights from all of the inventors.[64] Without an assignment of those rights, the inventor may also have the sole authority to direct the patent attorney prosecuting the patent and not the university. Again, the preferable way to get or at least confirm title is through prompt execution of an assignment from the inventor to the university.

In those situations where there is no executed assignment, the university may be able to rely on employment contracts and university patent policies to establish an obligation by

the university researcher to convey their invention rights to the university.[65] In *Fenn v. Yale University,*[66] the court found that Fenn, a Nobel Prize recipient for his invention relating to mass spectrometry, violated Yale's patent policy by misrepresenting the invention's commercial value and discouraging Yale from seeking a patent on the invention. Fenn further assigned his rights to a company in which he had an ownership interest and refused to share the licensing revenues with Yale. Most importantly, the court ruled that, because of Yale's patent policy, Yale owned the rights to Fenn's invention and then awarded the university damages because Fenn's actions were "intentional and without justification." Although the Fenn case is a particularly egregious example, the important principle is that universities can protect themselves through employment contracts and patent policies against such conduct.[67]

In *Fenn,* the university researcher was subject to the university's patent policy through a written employment agreement. In *Regents of the University of New Mexico v. Knight,*[68] the University of New Mexico sought a ruling from the Federal Circuit on ownership of the patent rights on compounds for treating cancer invented by a faculty member (Scallen) and a faculty staff member (Knight). Scallen had signed an agreement each year that contained the university's patent policy obligating the faculty to assign the rights to the university and which the Federal Circuit ruled was binding on that faculty member. The University of New Mexico had to strain a little harder with Knight who, as a faculty *staff* member, did not sign such an agreement, but was nonetheless held by the Federal Circuit to by bound by implied contract under the University of New Mexico's patent policy.

What about research by those who are not university faculty or staff? In *Chou v. University of Chicago and Arch Development Corp.,*[69] the Federal Circuit ruled that a graduate student was obligated to assign her rights to the university by virtue of the university's patent policy.[70] In *University of West Virginia Board of Trustees v. Van Voorhies,* the Federal Circuit ruled a graduate student was obligated to assign his rights to the university by virtue of the university's patent policy and prior assignments of the parent patent applications.[71] As the *Chou* and *Van Voorhies* cases demonstrate, a university's patent policy can be extremely helpful in establishing ownership of the rights,

even where there is no employment agreement and where the individual involved in the inventive activity is other than university faculty or staff.

What makes the resolution of such ownership disputes between the university and its researchers more difficult is that these disputes generally involve state law, so the specific resolutions may vary from one state to another.[72] The university must also be diligent in pursuing ownership claims from a researcher who fails to assign their rights. In *University Patents Inc. v. Kligman,*[73] the court found that the university's patent policy would have created an implied obligation on the university professor to assign its rights. Unfortunately for the university, the court also ruled that its suit to enforce that obligation was barred by the statute of limitations.

Even when the university researcher assigns their invention rights to the university, there are other issues to be aware of in such assignments. An obvious one is that the assignment should provide the university with the right to pursue the patent throughout the world. Any limitations on transfer of rights in the assignment may also turn the assignment into a license.

What may surprise a university is that a contractual agreement to assign rights to future inventions *does not create an assignment* of those rights.[74] In the second round of *University of West Virginia Board of Trustees v. Van Voorhies (Van Voorhies II),*[75] the former graduate student also refused to assign his rights to a second-generation patent. The Federal Circuit ruled in *Van Voorhies II* that the assignment of the original patents did not apply to the second-generation patent.[76] However, the Federal Circuit left open whether the university's patent policy might cover the second-generation patent.[77]

An often-overlooked right that should be included in the assignment is the right of the university to sue for past infringement. The right to sue for past infringement allows the collection of damages that occurred prior to the execution of the assignment. This may be a very important, as well as a valuable right, if the assignment by the inventor occurs many years after the patent is granted or even published.[78] The reason that the right to sue for past infringement should be included in the assignment is that courts have held

that such a damage clause cannot be transferred separate from the patent itself.[79] Although no particular language is required to transfer the right to sue for past infringement, the mere assignment of the patent does not operate to cause such a transfer.

Obligations to University Inventors

While the university's employment agreement or patent policy can obligate the university inventor to transfer his or her invention rights to the university, the same agreement/patent policy may say nothing about the university's obligations to the university inventor. Universities may owe some implied obligations to university inventors under these agreements/patent policies, including avoiding abuses of discretion and bad faith in dealing with university inventors.[80] For example, in *Signer v. University of California,* a jury found that the university abused its discretion when it divided the total revenues into research funds and royalties and gave the university inventors only a portion of the royalties.[81]

However, in the absence of such bad faith, abuse of discretion, or other express agreement, what obligations the university owes to the university inventor because of the university's patent policy are typically within the university's discretion. For example, courts have found that a university inventor cannot: (1) assert that the university has no right in the patent by claiming the university did not accept the invention within the time period provided by the patent policy,[82] (2) regain ownership for failure to obtain a royalty licensee based on the patent policy,[83] or (3) use the university's patent policy to obtain damages as a result of the university's decision not to pursue potential infringers.[84] The university also has discretion in selecting the licensee, determining the royalty terms, whether to license the patent at all, or simply return the rights in the invention back to the inventor.

Written Description/Enablement Requirement as Applied to Unpredictable Technologies

The written description/enablement requirement can be troublesome in drafting patents for all technologies, especially when trying to secure broad patent protection. This requirement can be especially difficult for certain unpredictable technologies, such as biotechnology and pharmaceuticals, which are at the heart of much university research.

The recent cases of the *University of Rochester v. G.D. Searle & Co.* and *In re Wallach* are painful reminders that the impact of the written description/enablement requirement on unpredictable technologies is not going away anytime soon.

What Technologies Are Considered Unpredictable?

One of the requirements in getting a patent is that the claimed invention not be obvious to one of ordinary skill in the art.[85] The ability to overcome this obviousness standard in patenting certain technologies has been aided by the perception that they are an unpredictable art. These unpredictable arts include catalysis, pharmaceuticals, and, most recently, biotechnology. The perception that these technologies, and especially biotechnology, are unpredictable tends to negate obviousness, making it easier to demonstrate that the biotechnology invention is patentable.

Many broad biotechnology and pharmaceutical patents claim the invention in terms of its *functional* characteristics, rather than its chemical structure, to obtain broader coverage. For example, some biotechnology patents claim the gene in terms of its ability to encode a class of proteins that are functionally analogous to a particular protein, or claim the protein (e.g., hormone) in terms of its activity.[86] Similarly, some pharmaceuticals patents have tried to claim drugs or methods for treating certain conditions with drugs in terms of the mechanism or biological pathway by which the drug works.[87]

Impact of Written Description/Enablement Requirement on Getting Broad Patent Coverage on Unpredictable Technologies

As owners of these broad biotechnology and pharmaceutical patents have unfortunately found out, the perception of biotechnology and pharmaceuticals as unpredictable is a double-edged sword. To be valid, a patent must also contain "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art" to make and use the invention.[88] This is referred to hereafter as the *written description/enablement requirement.* The predictability as to what will (and will not) work usually determines how much of the claimed invention satisfies the written description/enablement requirement.

This written description/enablement requirement has proven to be a significant barrier to getting and then enforcing broad biotechnology patents, as well as certain broad pharmaceutical patents. Indeed, broad functionalized biotechnology patent claims have generally not faired well in the courts. The Federal Circuit has applied a fairly stringent written description/enablement requirement to such broad functionalized claims because of the perceived unpredictability of biotechnology and pharmaceuticals. This stringent standard has been difficult to satisfy, especially since the litigated patents typically have only one or a few working examples of the claimed invention.[89]

The difficulty in satisfying this stringent standard in the biotechnology area has led alternatively to claims limited to genes or the encoded proteins that are *specifically exemplified* in the patent. However, as the litigated patents also show, the potential infringer may slightly alter the gene or encoded protein, and, thus, avoid infringing such narrow patent claims.[90]

The problem of patenting biotechnology, as well as pharmaceuticals, broadly has been further complicated by a recent, but subtle conflict between the two distinct components of this requirement, namely *written description* and *enablement.* Prior to 1997, written description was considered as primarily relating to whether the inventor had possession of the invention at the time the patent was filed, i.e., whether the later belief by the inventor as to what the invention was real or an afterthought. Indeed, up through 1997, enablement was the primary barrier to getting broad biotechnology patents.[91] However, in the case of *Regents of the University of California v. Eli Lilly & Co.,*[92] the Federal Circuit articulated another feature of written description, namely, whether the invention had been adequately described in the specification so that one skilled in the art would know what it is. In *Regents of the University of California,* the Federal Circuit ruled that simply referring to DNA for human insulin did not adequately describe what it was, i.e., what was the *chemical structure* of this DNA.

This adequate description feature of written description has become the new barrier to patenting biotechnology broadly. The Federal Circuit has not helped this situation by sometimes blurring the distinction between written description and enablement. This

blurring first occurred in *Enzo Biochem, Inc. v. Gen-Probe, Inc.,* where a three-judge panel of the Federal Circuit (one judge dissenting) affirmed a grant of summary judgment by a federal district court invalidating patent claims on nucleic acid probes that selectively hybridized to genetic material of bacteria that cause the venereal disease, gonorrhea.[93] While these patent claims were invalidated for failing to satisfy written description, the Federal Circuit's language in the *Gen-Probe* case, and especially the reliance on prior Federal Circuit cases involving enablement, started to blur this distinction. This possible blurring was left unresolved when the same three-judge panel reheard, and then reversed, its prior decision by holding that these patent claims might satisfy written description based on a biological deposit of the nucleotide sequences.[94]

Unfortunately for university research, written description is very much alive and well. In the recent case of *University of Rochester v. G.D. Searle & Co.,* a federal district court had to decide whether the University of Rochester's Young patent[95] satisfied written description, as well as enabled one skilled in the art to practice the claimed method. The Young patent broadly claimed a method for treating pain and inflammation by inhibiting the pain-causing COX-2 enzyme, but not the beneficial COX-1 enzyme. Indeed, the Young patent described in detail the mechanism and biological pathway by which pain and inflammation relief could be achieved without undesired side effects, as well as a screening assay for identifying potential drugs.

The district court found that the Young patent did "not identify any particular drugs that the assay will identify as suitable for" pain and inflammation relief. Instead, the Young patent provided only a general, vague listing of compounds from which the screening assay might identify suitable drugs. In fact, only one specific compound was identified by the patent that might be suitable in the claimed method. Accordingly, the district court ruled that the Young patent was invalid for failing to satisfy written description, as well as not being enabled. The Federal Circuit later affirmed, but solely on the basis of failure to satisfy written description.

In another recent case, the Federal Circuit suggests it may be easing the stringent application of the written description standard to biotechnology, but not completely. In *In re*

Wallach, the Federal Circuit has at least conceded that knowledge of the complete amino acid sequence of protein is sufficient to establish knowledge of the DNA encoding that protein. However, the Federal Circuit was unwillingly to say that knowledge of 11 amino acids in a sequence of a protein (TBP II) having 185 to 192 amino acids was sufficient to show possession of the DNA encoding the entire protein, and ruled that written description was not satisfied.

Dealing with the Written Description/Enablement Requirement in an Unpredictable World

The hard lesson from the *University of Rochester* case is that discovery of a drug pathway, without more, may not be enough to support broad method of treatment claims that will survive the written description/enablement requirement. *In re Wallach* is further a warning that trying to claim biotechnology broadly with minimal knowledge of the specific amino acid-nucleotide sequences involved can still run afoul of this requirement.

So how does a university get broad patent claims in unpredictable arts, such as biotechnology and pharmaceuticals? Here are some suggestions:

1. *Exemplify as much as possible in the patent disclosure the scope of the technology being claimed.* This includes how to make and how to use the claimed technology. It is also important to understand as much as possible the operative limits of the claimed technology and to put *all* of that knowledge into the patent disclosure. Be careful in relying exclusively on illustrative or prophetic examples without actually testing a representative selection of such examples to see if they do work. The litigated patents have shown the danger of relying on such examples when they later turn out not to work. Also, make sure each term, component, and step recited in the patent claim is defined in sufficient detail. As one case painfully demonstrates, reliance on general teachings in the art can be extremely risky in the biotechnology area.[96] In the pharmaceutical area, identify as many *specific* compounds as possible that will or might satisfy the discovered mechanism for treatment. This may involve some risk (see prior discussion regarding illustrative or prophetic examples), but the *University of Rochester* case makes such identification imperative.

2. *Augment the initial patent disclosure by filing continuation or provisional patent applications to include new working examples or new understandings about the technology.* To preserve patent rights in absolute novelty countries such as Europe, it is not unusual for a patent application to be filed with broad claims, but with only a few or possibly only one working example disclosed. Rather than rely on what later may be held to be inadequate written description/enablement, consider filing continuation or provisional patent applications to include new working examples or new understandings of the technology. Provisionals are especially valuable for doing multiple filings (at relatively low cost) to augment the initial patent disclosure. For example, five provisional patent applications can be filed in the United States for about the cost of one nonprovisional patent application. Provisional patent applications also should not be treated as an excuse for a sloppy patent filing, such as simply slapping a provisional cover sheet on a journal article or abstract unless time constraints dictate otherwise. Each provisional patent application must still satisfy the written description/enablement requirement,[97] and should, therefore, be treated as if it were a nonprovisional patent application.
3. *Where possible, pursue broad method claims, including methods for making the gene or protein or using the gene or protein.* Do not overlook the value of getting patent coverage on the method for making the gene or protein. Under appropriate circumstances, importation of the gene, and, more importantly, the protein, into the United States can be prevented if the gene or protein is made by a patented method. Indeed, one court case that prevented importation of hGH made by a patented method involving recombinant DNA suggests broad method claims for making genes or proteins may be less likely to run afoul of the written description/enablement requirement.[98] Also, consider claiming the gene or protein for use as probe, a screening assay for the drugs, a DNA microchip, etc.

The perceived unpredictability of certain technologies such as biotechnology and pharmaceuticals makes it more difficult for universities to get enforceable broad claims on such technology. However, the courts have also made clear that broad patent coverage on unpredictable technologies is not precluded. The challenge for universities is to craft patent disclosures that will satisfy the more stringent written description/enablement standard applied to these "unpredictable" arts.

Notes

1. For a more detailed discussion of the experimental use defense, see E. Guttag, "Immunizing University Research from Patent Infringement: the Implications of *Madey v. Duke University,*" 15 *AUTM J.* 1 (December 2003); republished in 18 *Ind. & High. Edu.* 156 (June 2004).
2. The courts, commentators, and others have referred to the experimental use defense variously and interchangeably as a "defense," "exception," or "exemption." See also L. Bruzzone, "The Research Exemption: A Proposal," 21 *AIPLA Q. J.* 52, 53 (1993) (calling it the "research exemption").
3. See 17 U.S.C. §107 (1996); see also M. O'Rourke, "Toward a Doctrine of Fair Use in Patent Law," 100 *Colum. L. Rev.* 1177, 1181-1211 (2000), which discusses the development of the copyright "fair use" doctrine and its potential application to patent law.
4. See *Whittemore v. Cutter,* 29 F. Cas. 1120 (C.C.D. Mass. 1813); *Sawin v. Guild,* 21 F. Cas. 554 (C.C.D. Mass. 1813).
5. See R. Hantman, "Experimental Use as an Exception to Patent Infringement," 67 *J. Pat. & Trademark Off. Soc'y* 617, 620 (1985).
6. See S. Michel, "The Experimental Use Exception to Infringement Applied to Federally Funded Inventions," 7 *High Tech. L.J.* 369, 372 (1992); R. Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use," 65 *U. Chi. L. Rev.* 1017, 1074-75 (1989).
7. Michel, supra note 6 at 372.
8. Id., see Eisenberg, supra note 6 at 1074-75 (1989) (strongest case for "experimental use" exception); I. Feit, "Biotechnology Research and the Experimental Use Exception to Patent Infringement," 71 J. PAT. & TRADEMARK OFF. SOC'Y 819, 833 (1989) (protected activities include "ascertaining the verity and exactness of the specification").
9. *Madey v. Duke University,* 307 3d. 1351, 1361-62, 64 U.S.P.Q.2d (BNA) 1737, 1746 (Fed. Cir. 2002).
10. 307 3d. 1351, 64 U.S.P.Q.2d (BNA) 1737 (Fed. Cir. 2002).
11. 733 F.2d 858, 221 U.S.P.Q. (BNA) 937 (Fed. Cir. 1984).
12. 216 F.3d 1343, 55 U.S.P.Q.2d (BNA) 1161 (Fed. Cir. 2000).

13. In 1988, Congress proposed a statutory research exemption that died in Senate subcommittee. In 1990, Representative Kastenmeier introduced another bill (H.R. 5998) that would have made the experimental use defense statutory that also was not enacted. Congress has not renewed the effort to make the experimental use defense statutory. See Thayer et al, "The Research Exemption to Patent Infringement: The Time Has Come for Legislation," 4 *J. Biolaw + Bus.* 1, 21 (2000).
14. For a more in-depth discussion of the affect of sovereign immunity on technology rights transfer by state universities, see C. Shores, "State Sovereign Immunity and Technology Transfer," 2003 *AUTM* J. 21 (December 2003).
15. 527 U.S. 627, 51 U.S.P.Q.2d (BNA) 1081 (1999). Interestingly, it was assumed that the Florida Prepaid Postsecondary Education Expense Board was "an arm of the State of Florida." Id. at 633, 51 U.S.P.Q.2d (BNA) at 1084, n 3.
16. In the Intellectual Property Restoration Act of 2003 (S. 1191 and H.R. 2344), Congress would allow the state to obtain intellectual property rights, including patents, but would condition enforceability of such rights to obtain money damages on the state waiving its sovereign immunity against intellectual property suits by private parties. Shores, supra note 14 at 35 (2003). The prospect of such legislation being enacted is uncertain, and, if enacted, will likely be challenged again on constitutional grounds. See Shores, supra note Id. at 36-39.
17. State universities qualify for sovereign immunity under the Eleventh Amendment as an arm of the state. *Xechem International, Inc. v. The University of Texas M.D. Cancer Center,* 382 F.3d. 1324, 72 U.S.P.Q.2d (BNA) 1253 (Fed. Cir. 2004) (University of Texas an arm of the State of Texas). See also *Hutsell v. Sayre,* 5 F.3d 996, 999-1000 (6th Cir. 1993), *cert. denied,* 510 U.S. 1119 (1994) (University of Kentucky an arm of the State of Kentucky).
18. The mere appearance of the state university in federal district court to defend against such a patent infringement suit does not constitute such "voluntary participation" that would waive sovereign immunity under the Eleventh Amendment. *State Contr. & Eng'r. Corp. v. Florida*, 258 F.3d at 1329, 1336, 59 U.S.P.Q.2d (BNA) 1498, 1503 (Fed. Cir. 2000), *cert denied,* 122 S.Ct. 1072 (2002).
19. See *The Regents of the Univ. of New Mexico v. Knight,* 321 F.3d 1111, 66 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 2003). The *Knight* case involved a dispute between the University of New Mexico and two professors (Dr. Scallen and Dr.

Knight) over patent rights in some compounds for treating cancer. When the University of New Mexico brought suit in federal district court against these professors to declare who owned the patent rights, Knight filed counterclaims against the University of New Mexico for various contract and tort actions, including breach of contract, intentional interference with prospective economic advantage, abuse of process, slander, and breach of fiduciary duty. While the Federal Circuit ruled that the University of New Mexico owned the patent rights, they also ruled that Knight's counterclaims were not barred by sovereign immunity under the Eleventh Amendment because the University of New Mexico had "waived" it by filing suit against Knight in federal district court.

20. 382 F.3d 1324, 72 U.S.P.Q.2d (BNA) 1253 (Fed. Cir. 2004) (unsuccessful request to correct inventorship in patent application filed by the University of Texas).
21. Now codified variously as 21 U.S.C. §§ 355, 360 (1999 & Supp. 2003) and 35 U.S.C. §§156, 271, 282 (2001).
22. Now codified as 35 U.S.C. §271(e)(1) (1999), which states in relevant part: "It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."
23. 496 U.S. 661, 675-97, 15 U.S.P.Q.2d (BNA) 1121, 1124-30 (1990).
24. Other matters that are subject to regulatory approval and/or review by the FDA include food additives and cosmetics. See 21 U.S.C. §341, §361 (1999 & Supp. 2003).
25. 28 U.S.C. §1498(a) says, in relevant part: Whenever an invention described in and covered by a patent of the United States is *used* or *manufactured by or for the United States* without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. . . .

For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States *by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.* (Emphasis added.)

26. See J. Welch, "Patent Infringement in Government Procurement: GAO's Role," 51 *J. Pat. Off. Soc'y* 177, 178 (1969), which discusses the history and genesis of 28 U.S.C. §1498(a). See also J. Davis, "Trial of Patent and Copyright Cases in the U.S. Court of Claims," 57 *J. Pat. Off. Soc'y* 253 (1975); J. Colaianni, "Damages in the U.S. Claims Court," 66 *J. Pat. Off. Soc'y* 3 (1984). As originally enacted, 28 U.S.C. §1498(a) was construed not to protect federal contractors who could thus be enjoined from infringing the patent. *Cramp & Sons v. Curtis Turbine Co.,* 246 U.S. 28 (1918). This led Congress to modify the original act, now codified in the second portion of 28 U.S.C. §1498(a) quoted in note 25 supra. See Welch, supra at 178.
27. Preferably a written obligation of confidentiality.
28. Europe does provide a grace period of six months to file the patent in Europe if someone breaches the obligation of confidentiality.
29. 35 U.S.C. §102(b) which says, in relevant part: "A person shall be entitled to a patent unless: (b) the invention was described in a printed publication in this country or in a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States. ... ." . An invention is "on sale" if it is either sold or offered for sale.
30. 35 U.S.C. §102(b) and the cases refer to "printed publication;" for simplicity the term "printed" has been omitted.
31. 380 F.3d 1345, 72 U.S.P.Q.2d (BNA) 1117 (Fed. Cir. 2004). More than a year prior to filing the patent, the inventors had presented a printed slide presentation a scientific meeting of those having the level of knowledge to understand the presentation. The presentation was printed and pasted on poster boards and was displayed continuously for two-and-a-half days at the meeting. One month later, the same slide presentation was put on display for less than half a day at a state university.

32. See *In re Croyn,* 890 F.2d 1158 (Fed Cir. 1989) (college student presentation of undergraduate thesis to defense committee of four faculty members not "publication"); *In re Hall,* 781 F.2d 897 (Fed Cir. 1986) (thesis filed and indexed in university library was "publication"); *Massachusetts Institute of Technology v. AB Fortia,* 774 F.2d 1104 (Fed Cir. 1985) (paper delivered orally to First International Cell Culture Congress was "publication"); cf. *In re Wyer,* 655 F.3d 221 (CCPA 1981) (Australian patent application kept on microfilm at Australian Patent Office was "publication").
33. The Federal Circuit ruled that the inventors' slide presentation was a "publication" because it was shown: (1) to a wide variety of viewers, a large portion of who possessed the requisite knowledge to understand it; (2) for approximately three cumulative days; (3) with no stated expectation that the information would not be copied or reproduced by those viewing it.
34. 380 F.3d at 1349, 72 U.S.P.Q.2d (BNA) at 1120, fn. 4.
35. See Section C infra. If oral presentations at scientific meetings are considered to be a "public use," there will still be the evidentiary issue of exactly what was revealed by the oral presentation. Unlike a printed presentation that is relatively fixed in terms of what was disclosed, it may be much more difficult to establish exactly what was revealed by an oral presentation, especially as time goes by.
36. Printed or oral presentations at scientific meetings will also likely impact patent rights in countries having an "absolute novelty" standard.
37. 525 U.S. 55, 67 (1998).
38. 365 F.3d 1306, 70 U.S.P.Q.2d (BNA) 1737 (Fed. Cir. 2004).
39. The patent was nonetheless invalidated in view of a prior SmithKline patent.
40. See *Mas-Hamilton Group v. LaGard, Inc.,* 156 F.3d 1206, 48 U.S.P.Q.2d (BNA) 1010 (Fed. Cir. 1998); *In re Kollar,* 286 F.3d 1326 (Fed. Cir. 2002).
41. Id.; see also *Elan Corp. v. Andrx Pharmaceuticals, Inc.,* 366 F.3d 1336, 70 U.S.P.Q.2d (BNA) 1722 (Fed. Cir. 2004).
42. Id.
43. 286 F.3d 1326 (Fed. Cir. 2002).
44. 286 F.3d at 1333 (such a transaction is not "sale" of the invention within the meaning of 35 U.S.C. §102(b)).
45. 366 F.3d at 1336, 70 U.S.P.Q.2d (BNA) 1722 (Fed. Cir. 2004).

46. See *Varrin v. Queen's University,* No. 01 C 9297, 2002 WL 31001890 *2 (N.D. Ill. Sept. 3, 2002) (allowing dispute between Canadian inventor and Canadian university to proceed because U.S. patent involved inventorship issues that must be decided before determining ownership).
47. See *Frank's Casing Crew & Rental Tools, Inc., v. PMR Technologies, Ltd,* 292 F.3d 1363, 63 U.S.P.Q.2d (BNA) 1065 (Fed. Cir. 2002) (deliberate omission of inventor rendered patent unenforceable for inequitable conduct).
48. See *Board of Education Ex. Rel. Board of Trustees of Florida State University v. American Bioscience, Inc.,* 333 F.3d 1330, 1340 (Fed. Cir. 2003) (actual reduction to practice not required to establish conception).
49. *University of Colorado Foundation, Inc. v. American Cyanamid Co.,* 105 F.Supp.2d 1164, 1176 (D. Colo. 2000).
50. See *Jamesbury Corp. v. U.S.,* 518 F.2d 1384, 1396 (Ct. Cl. 1975).
51. 342 F.3d 1298 (Fed. Cir. 2003).
52. 233 F.Supp.2d 1282 (D. Or. 2002).
53. It is unclear why another patent was not filed (possibly as a continuation-in-part) with a new claim set covering nonbinder subject matter discovered by the university researcher.
54. A "developed" project should not be confused with a R&D project that is organized to be carried out in stages.
55. See *Brown v. Regents of University of California,* 866 F. Supp. 439, 445 (N.D. Cal. 1994) (technician not involved in laboratory to reduce the compounds to practice); *Jamesbury Corp. v. U.S.,* 518 F.2d 1384, 1396 (Ct. Cl. 1975) (person who merely follows instructions of another in performing experiments is not co-inventor). See also *Williams Service Group, Inc. v. O.B. Cannon & Son, Inc.,* 33 U.S.P.Q.2d (BNA) 1705, 1727 (E.D. Pa. 1994) (each co-inventor must make some contribution to "inventive thought").
56. See *Dennison Mfg. Co. v. Ben Clements and Sons, Inc.,* 467 F. Supp. 391, 424 (D.C.N.Y. 1979) (obvious variant on conception was non-inventive); *Willens v. Breen,* 343 F.2d (BNA) 477, 481 (C.C.PA. 1965) (contributions suggest obvious improvement).
57. See *Regents of University of California v. Symbiotics Corp.,* 29 U.S.P.Q.2d (BNA) 1463, 1463 (S.D. Cal. 1993) (only suggesting broad idea that is obvious in view of prior art is not joint invention).

58. See *Board of Education Ex. Rel. Board of Trustees of Florida State University v. American Bioscience, Inc.,* 333 F.3d 1330, 1340 (Fed. Cir. 2003) (having in mind specific portions of claimed compound not same as conceiving the compound with all its components).
59. See *Regents of University of Michigan v. Bristol-Myers Squibb Co.,* 301 F.Supp.2d 633, 644 (E.D. Mich. 2003) (informing the named inventors of publicly available information is not conception or inventive contribution).
60. See *Sprinturf, Inc. v. Southwest Recreational Industries, Inc.,* No. Civ.A. 01-7158, 2004 WL 524427 *4 (E.D. Pa. March 12, 2004) (university researcher's contributions part of prior art).
61. See *Huang v. California Institute of Technology,* 72 U.S.P.Q.2d (BNA) 1161, 1166 (D. Cal. 2004); *Board of Education Ex. Rel. Board of Trustees of Florida State University v. American Bioscience, Inc.,* 333 F.3d 1330, 1340 (Fed. Cir. 2003) (no clear and convincing evidence of misjoinder of inventors). See also *Frank's Casing Crew & Rental Tools, Inc., v. PMR Technologies, Ltd,* 292 F.3d 1363, 63 U.S.P.Q.2d 1065 (Fed. Cir. 2002) (deliberate omission of inventor rendered patent unenforceable for inequitable conduct).
62. See *Regents of University of Michigan v. Bristol-Myers Squibb Co.,* 301 F.Supp.2d 646 (E.D. Mich. 2003) (by time university inventor contributed, company already had invention). Conversely, this stringent standard has also prevented industry from improperly obtaining an ownership interest in a university's patent. See *MediGene AG v. Loyola University of Chicago,* No. 98 C 2026, 2001 WL 1636425 *1 (N.D. Ill. Dec 19, 2001).
63. For a more detailed discussion on a university researcher's obligation to assign their rights and on the enforceability of university patent policies in this regard, see N. Ohashi, "The University Inventor's Obligation to Assign: A Review of U.S. Case Law on the Enforceability of University Patent Policies," 15 *AUTM J.* 49 (December 2003).
64. 270 F.Supp.2d 88, 89 (D. Mass. 2003) (inventorship error occurred after the filing patent, university was unable to get assignment from unnamed inventors).
65. It should be noted that if the university inventor used the university's materials, facilities, etc., in conceiving and reducing to practice the invention, the university may have a nonexclusive license to use the invention under the "shop right" doctrine.

66. 283 F.Supp.2d 615 (D.Conn. 2003).
67. The court rejected Dr. Fenn's allegation that revisions of Yale's patent policy made it ineffective and instead found these revisions did not impact the basic employment relationship, i.e., Dr. Fenn's inventions belonged to Yale.
68. 321 F.3d 1111 (Fed. Cir. 2003).
69. 254 F.3d 1347 (Fed. Cir. 2001).
70. In *Chou,* the graduate student was an unnamed inventor who sought to be added as an inventor and share in the royalties; the patent policy, while transferring ownership to the university, did not prevent the unnamed graduate student from seeking to correct inventorship.
71. 278 F.3d 1288, 1298 (Fed. Cir. 2002).
72. See *E.I. Du Pont de Nemours & Co. v. Okuley,* 344 F.3d 578, 583 (6th Cir. 2003) (claim to the sole ownership of invention does not invoke federal patent law jurisdiction); *Biby v. Board of Regents of University of Neb. at Lincoln,* 2004 WL 2191171, *9 (D. Neb. Sept. 29, 2004) (any challenge to the patent's ownership, raises question of state law."); *Chou v. University of Chicago,* 254 F.3d 1347, 1356-57 (Fed. Cir. 2001) (ownership governed by Illinois law); *Regents of University of New Mexico v. Knight,* 321 F.3d 1111 (Fed. Cir. 2003) (ownership governed by New Mexico law).
73. 1991 WL 64652 (E.D.Pa. April 22, 1991).
74. See *Arachnid, Inc. v. Merit Industries, Inc.,* 939 F.2d 1574, 1580 (Fed. Cir. 1991) (provision that all rights to inventions developed during the consulting period "will be assigned" did not rise to the level of assignment of existing invention, effective to transfer all legal and equitable rights therein).
75. 342 F.3d 1290 (Fed. Cir. 2003).
76. 342 F.3d at 1296-97 (Fed. Cir. 2003) (university conceded that second generation patents were outside scope of the assignment agreement).
77. 342 F.3d at 1296. While continuations-in-part of the original patents were covered by the assignment and/or the university's patent policy, it was unclear whether these explicitly or implicitly provided the university any ownership rights in the second generation patents.
78. See 35 U.S.C. § 154(d) (provisional right to obtain royalties for infringement after publication date of patent).

79. See *Minco, Inc. v. Combustion Engineering, Inc.,* 95 F.3d 1109 (Fed. Cir. 1996) (right to sue for prior infringement not transferred unless assignment agreement manifests intent to transfer this right).
80. See *Kucharczyk v. Regents of University of California,* 48 F.Supp.2d 964, 971 (N.D. Cal. 1999) (provisions from the university's patent policy that were incorporated in the assignment agreement and patent agreement imposed some contractual obligations upon the university).
81. 40 U.S.P.Q.2d (BNA) 1035, 1038 (Cal. Sup. Ct. 1996) (awarding damages to the university inventors based on total revenues of $22 million that had been divided by the university into $20 million for research and $2 million for royalties).
82. See *Biby v. Board of Regents of University of Neb. at Lincoln,* 2004 WL 2191171 *9 (D. Neb. Sept. 29, 2004) (finding that this fact was negated by the later execution of the assignment document, even though the inventor claimed he was coerced).
83. See *Kucharczyk v. Regents of University of California,* 946 F. Supp. 1419, 1431 (N.D. Cal. 1996) (summary of patent guidelines not part of the patent policy and therefore no obligation to obtain a running royalty based on that policy).
84. See *Signer v. University of California,* 40 U.S.P.Q.2d (BNA) 1035 (Cal. Sup. Ct. 1996) (no duty in patent policy, claim too speculative).
85. 35 U.S.C. §103(a).
86. See, e.g., *Enzo Biochem, Inc. v. Gen-Probe, Inc.,* 296 F.3d 1316 (Fed. Cir. 2002) (probes characterized in terms of minimum hybridization ratio, rather than particular nucleotide sequences that would have minimum ratio).
87. See, e.g., *University of Rochester v. G.D. Searle & Co., Inc.,* 358 F.3d 916, 69 U.S.P.Q.2d (BNA) 1886 (Fed. Cir. 2004) (method for selectively inhibiting COX-2 activity by administering non-steroidal compound that selectively inhibits activity of COX-2 gene product).
88. 35 U.S.C. §112 ¶1. See also *PTO's Guidelines for Examination of Patent Applications Under the 35 U.S.C.* 112, ¶1, "Written Description" Requirement, 66. Fed. Reg. 1099.
89. See, e.g., *Enzo Biochem, Inc. v. Calgene, Inc.,* 188 F.3d 1362 (Fed. Cir. 1997) (broad patent claims covering antisense technology invalid for lack of enablement because of absence of sufficient working examples).

90. See, e.g., *Regents of University of California v. Eli Lilly Co.,* 119 F.3d 1559, 43 U.S.P.Q.2d (BNA) 1398 (Fed. Cir. 1997) (patent covered DNA that coded proinsulin, but not proinsulin-containing fusion protein).
91. See *Genentech, Inc. v. Novo Nordisk, A/S,* 108 F.3d 1361, 42 U.S.P.Q.2d (BNA) 1001 (Fed. Cir. 1997); *Enzo Biochem, Inc. v. Calgene, Inc.,* 188 F.3d 1362 (Fed. Cir. 1997).
92. 119 F.3d 1559, 43 U.S.P.Q.2d (BNA) 1398 (Fed. Cir. 1997).
93. 296 F.3d 1316 (Fed. Cir. 2002).
94. As it soon turned out, that was not the end of the "blurring" issue. A subsequent petition for rehearing en banc was denied when the six judges of the Federal Circuit hearing the petition split 3-3, with three concurring opinions and two dissenting opinions that expressed a tremendous difference in viewpoint on what "written description" means, and even the potential correctness of prior Federal Circuit decisions that had articulated what "written description" meant.
95. U.S. Patent 6,048,850, alleged to be infringed by Pfizer's Celebrex drug for pain and inflammation relief. The stakes were high because three other companies also were alleged to infringe this patent.
96. *Enzo Biochem, Inc. v. Calgene, Inc.,* 188 F.3d 1362 (Fed. Cir. 1997).
97. *Cf. New Railhead Mfg. v. Vermeer Mfg. Co.,* 298 F.3d 1290, 63 U.S.P.Q.2d (BNA) 1843 (Fed. Cir. 2002).
98. See *Bio-Technology General Corp. v Genentech, Inc.,* 267 F.3d 1325, 60 U.S.P.Q.2d (BNA) 1430 (Fed. Cir. 1996).

Mask Works and Semiconductors

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Introduction and Background

In the United States, the Semiconductor Chip Protection Act of 1984 (Chip Act)[1] provides a mechanism for protecting the topology of mask works associated with semiconductor chips. The topology includes three-dimensional images or patterns formed of metallic, insulating, or other semiconductor material.

The Chip Act was originally intended to provide a benefit to those who invest in chip research, development, and production at a time when patent protection and copyright protection was often not obtainable on semiconductor chips. The Chip Act was intended to prevent competitors from reverse engineering a chip layer by layer and then generating a copy of the chip from this information.

Despite the availability of protection since enactment in 1984, there have been reasonably few mask-work registrations and very few reported law suits brought under the Chip Act. For example, in the U.S. Copyright Office's fiscal year 2003, there were 397 mask-work registrations and seven refusals to register mask works (five for ineligible material and two for being outside of the two-year filing deadline).[2] One rationale for the relatively few registrations is that there are easier ways to create competitive products than through infringement and that the protection offered is narrow in scope and short in duration compared to patent and copyright protection, respectively.

One may speculate that there may be more interest in mask-work protection in the near future due to increased work in areas such as biochips and nanotechnology. In the appropriate cases, mask-work protection may provide a reasonably inexpensive and relatively quick manner of obtaining intellectual property rights to at least supplement other types of protection.

Rights and Limitations of Rights

The owner of a mask work has certain exclusive rights and limitations on these rights. The owner of a mask work has the exclusive right to (1) reproduce the mask work by optical, electronic, or any other means; (2) to import or distribute a semiconductor chip product in which the mask work is embodied; and (3) to induce or knowingly to cause another person to reproduce the mask work or import or distribute a semiconductor product embodying the mask work.[3]

Reverse Engineering

One limitation of the exclusive rights of an owner of a mask work relates to reverse engineering. Reverse engineering of a mask work is permitted by law and provides an affirmative defense to a claim of infringement.[4] However, reverse engineering of mask work is allowed solely for the purposes of teaching, analyzing, or evaluating the concepts or techniques embodied in the mask work or in the circuitry, logic flow, or organization of components used in the mask work.[5] If the reverse engineering is legitimate, the person performing the reverse engineering may incorporate the results in an original mask work, which may be distributed.[6]

First Sale

Another limitation on the rights of a mask-work owner relates to the first sale. Purchasers of semiconductor chips have the right to use and resell them freely under the Chip Act, however, they may not reproduce them without the permission of the owner of the mask work embodied in the semiconductor chip product.[7]

Loss of Rights

If registration of a mask work does not occur within two years of its first commercial exploitation, the right to mask-work protection will be lost. Also, rights are lost after the expiration of the registration.

Duration of Rights

Mask-work protection lasts for a ten-year time period.[8] It begins on the earlier of (1) the date the mask work is registered with the U.S. Copyright Office or (2) the mask work is first commercially exploited anywhere in the world.[9] The ten-year time period expires at the end of the calendar year in which the protection would otherwise expire.[10]

Ownership

The exclusive rights in a mask work belong to the *owner*.[1] Ownership is analogous to that in copyrights as the owner of mask work is the person who created the mask work (or his or her legal representative if deceased or under a legal incapacity) or a party to whom all rights in the mask work have been transferred by a written instrument. If the mask work is made within the scope if a person's employment, the owner is the employer for whom the mask work was created unless the employer has transferred all rights by a written instrument.

Requirements for Protection: Originality and Fixation

Mask-work protection does not extend to any idea, procedure, process, system, method of operation, concept, principle, or discovery.[11] Instead, mask-work protection requires both originality and fixation. A design is original if it is independently created. To be original, the mask work must also be more than merely "designs that are staple, commonplace, or familiar in the semiconductor industry, or variations of such designs, combined in a way that, considered as a whole, is not original."[12] Fixation occurs once the mask work is sufficiently permanent or stable to permit the mask to be perceived or reproduced.[13]

Procedure for Registration

To register mask work through the U.S. Copyright Office, a Form MW is required along with the filing fee and deposit.[14] The deposit requirement depends upon whether or not the mask work has been commercially exploited or not.[15]

For a commercially exploited mask work, four chips as first commercially exploited are required along with one full set of visually perceptible reproductions of each layer of the mask work.[16] The visually perceptible reproduction requirement can be fulfilled by submitting plastic color overlays, composite plots, or photographs of each layer of the mask work.[17] For work that has not been commercially exploited, one full set of either plastic color overlays or composite plots of each layer of the semiconductor chip product is required; optionally, reproductions of the most complete form as fixed in a chip product may also be deposited.[18]

Notice Requirements

Notice of protection is not required, however, affixing a notice to mask works and semiconductor chip products embodying the mask work serves as prima facie evidence of notice of protection. Examples of an appropriate notice would include[19]

- Mask work Iowa State University
- *M* Iowa State University
- Ⓜ Iowa State University

Remedies

Once a certificate of registration is received from the U.S. Copyright Office, the owner of a mask work or exclusive licensee of all rights in the mask work, may bring a civil action for infringement occurring after commencement of protection. There have been few court cases involving mask-work infringement.[20] Statutory damages are as high as $250,000 or, alternatively, actual damages or the infringer's profits attributable to the infringement may be awarded.[21]

Transfer of Rights

The owner of the exclusive rights may transfer all of the rights or license all or fewer than all the rights to a third party. The transfer or license must be in writing and signed by the owner. The exclusive rights in a mask work may also be transferred by operation of law. Assignments and licenses may be recorded in the U.S. Copyright Office.

International Protection

Various other countries besides the United States provide equivalent or similar protection on semiconductors. Not all countries may have registration requirements.

Practical Considerations

Commercial Exploitation

The concept of *commercial exploitation* of mask works is important in several different respects. First, it sets a deadline as to when registration must take place (within two years of commercial exploitation), and, second, the date of commercial exploitation is used to measure the duration of protection (ten years from the earlier of registration or commercial exploitation).

The value of mask-work protection is closely tied to commercial exploitation. Registering a mask work prior to commercial exploitation may be disadvantageous as the length of protection is a period of ten years beginning from the effective date of registration or the first commercial exploitation. In some cases, the useful lifespan of the mask work may be less than ten years, so there may not be any benefit in waiting to register until just prior to commercial exploitation.

Not all Semiconductors Necessarily Protectable

Semiconductors do not necessarily require the use of a mask work in their fabrication process. Instead of using mask work, direct-writing techniques can be used. Thus, under the U.S. law, not all semiconductors can necessarily be protectable.

Other Forms of Protection for Semiconductors and Mask Works

Mask-work protection is generally considered a weak form of protection. Therefore, other forms of protection should be considered. Other forms of possible protection for semiconductors include patents and copyrights. Of course, the same innovation may be subject to different and multiple types of protection.

Notes

1. Semiconductor Chip Protection Act of 1984, 17 U.S.C. §§ 901-914 (2004).
2. Federal Register, Volume 69, Number 133, p. 42005 (July 13, 2004).
3. 17 U.S.C. § 905 (2004).
4. 17 U.S.C. § 906 (2004).
5. 17 U.S.C. § 906(a)(1) (2004).
6. 17 U.S.C. § 906(a)(2004).
7. 17 U.S.C. § 906(b)(2004).
8. 17 U.S.C. § 904(b)(2004).
9. 17 U.S.C. § 904(a)(2004).
10. 17 U.S.C. § 904(c)(2004).
11. 17 U.S.C. § 902(c)(2004).
12. 17 U.S.C. § 902(b)(2)(2004).
13. 17 U.S.C. § 901(a)(3)(2004).
14. *Federal Statutory Protection of Mask Works,* Circular 100, U.S. Copyright Office; *Form MW,* U.S. Copyright Office.
15. 37 C.F.R. § 211.5 (2004).
16. 37 C.F.R. § 211.5(b)(1) (2004).
17. 37 C.F.R. § 211.5(b)(1) (2004).
18. 37 C.F.R. § 211.5(b)(2) (2004).
19. 17 U.S.C. § 909(2004).
20. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555 (Fed. Cir. 1992).
21. 17 U.S.C. § 911 (2005).